EXHIBIT G

IN THE UNITED STATES DISTRICT COURT

FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEMS PRODUCTS LIABILITY LITIGATION

MASTER FILE NO. 2:12-MD-02327 JOSEPH R. GOODWIN

U.S. DISTRICT JUDGE

MDL NO. 2327

GENERAL CAUSATION RE: TVT-RETROPUBIC

PURSUANT TO NOTICE, the deposition of BRIAN J. FLYNN, M.D. was taken on behalf of the Plaintiffs at Denver Marriott West, 1717 Denver West Boulevard, Golden, Colorado on April 19, 2016, commencing at 1:08 p.m., before Melanie L. Giamarco, Registered Merit Reporter, Certified Realtime Reporter, and Notary Public within Colorado.

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I N D E X

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P R O C E E D I N G S

BRIAN J. FLYNN, M.D.,

after having been duly sworn, was examined and testified as follows:

EXAMINATION

BY MR. ZONIES:

Q. Good afternoon, Dr. Flynn. How are you today?

A. Very good, Mr. Zonies.

Q. As you know, Dr. Flynn, I represent plaintiffs in this litigation, and we're here today to take your deposition primarily about the TVT-Retropubic sling; is that your understanding?

A. That is.

MR. ZONIES: And I'll go ahead and mark as Exhibit 1 the notice of deposition as amended to show today's date.

(Exhibit 1 was marked for identification.)

Q. (By Mr. Zonies) Have you seen that notice of deposition before?

A. I have.

Q. And attached to that notice is a request for certain documents that might be in your possession, custody or control.

Did you bring any documents in response to

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that subpoena today?

A. Yes, I have.

Q. And what did you bring with you?

A. Okay. So I brought some e-mails that I've had in communication with Ethicon, J&J.

Q. And are these e-mails e-mails that we have previously marked in your earlier depositions?

A. That's correct. There is nothing new or different from the TVT-Secur or TVT-Obturator.

Q. Okay. And what else did you bring?

A. This is a contract that you've seen previously.

Q. Okay. Thank you. Anything else?

A. This is a fee schedule.

Q. Is this the same fee schedule we've previously marked as well?

A. Correct.

Q. All right.

A. This is my CV. And that hasn't been changed.

Q. So the same CV that we marked in your prior depositions?

A. Yes. This is trial and deposition history up until -- not including this recent round, so that hasn't been updated or changed since

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the last time I submitted it.

Q. Right. So the last testimony on here is the Perry case in --

A. That's correct.

Q. -- California, correct?

A. Yes. This is the notice of deposition, what you've just shown me as Exhibit 1.

Q. Okay.

A. Would you like that?

Q. Sure. I'll just keep a stack here.

A. Then this is new. These are my invoices on TVT. So there's two invoices here.

Q. Before we get to that, then, Doctor, everything you've just handed me prior to your invoices on TVT-Retropubic, we have previously marked in your earlier depositions.

MR. ZONIES: And Counsel, I will just say we'll incorporate those exhibits from those depositions rather than remark them all, if that's okay?

MS. SCHMID: Certainly. To the extent they've been previously marked, that's no problem.

MR. ZONIES: Okay. Great.

Q. (By Mr. Zonies) And you said you have something new, Doc?

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A. So these two binders in front of me are new. They contain articles that I've used in formulating my opinions. They contain my reliance list. They contain my TVT report, so similar to the other depositions. And I have, you know, a bibliography of my report and reliance list here that I use for convenience.

Q. Okay. So could I see the invoices, please?

MR. ZONIES: And we'll go ahead and mark these invoices Exhibit 2 and 3.

(Exhibits 2 and 3 were marked for identification.)

Q. (By Mr. Zonies) Doctor, I'm going to hand you what's been marked as Exhibit 2. Could you describe what that is, please?

A. This is Exhibit 2. It says "TVT Report." It has hours worked on this report which includes 15 hours to prepare the report at $500 an hour, and then there's a total of $7,500.

Q. And Doctor, does that represent all of the work that you did in the preparation of your TVT-Retropubic report for this case?

A. No, this was just for a two-month period, July and August of 2015.

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Q. Did you perform any work related to your TVT-Retropubic report prior to August of 2015?
A. No, I did not.
Q. And I'm going to hand you Exhibit 3. This appears to be an invoice subsequent to Exhibit 2 for the September time frame; is that right?
A. Yes. It's for the month of September 2015, 19 hours times $500 for a total of $9,500.
Q. So between those two invoices, there are 24 hours total for preparation of your report; is that correct?
A. Thirty-four.
Q. Thank you. Thirty-four. Told you, math -- I object when people try to do math. That's why.
So between those two invoices, Doctor, are 34 total hours for the preparation of your report in this case, correct?
A. That's correct.
Q. Other than those 34 hours, is there any other time that you spent on preparation of your report, your TVT-R report?
A. Of the report, no.
Q. And then your report was -- let me go

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ahead and mark your report.
(Exhibit 4 was marked for identification.)
Q. (By Mr. Zonies) I'm handing you what's being marked as Exhibit 4. Can you confirm for me, please, Doctor, that that's the report that you issued in this case concerning the TVT-Retropubic device?
A. This looks like a 46-page report, and it was signed by me on February 26. And it looks to be the same report. Without going through every page, it would be hard to say, but I got to believe it's the same report here.
Q. Okay. And if you see something that's different, let me know. But it's my understanding that this is what was issued as your report in February of 2016, okay?
A. Okay.
Q. The last time --
A. I do have one other thing to submit.
Q. Oh, sure.
A. Is a USB thumb drive. And this is labeled "TVT." What's on here would be things that aren't in these binders. So I try to do the best I can to avoid duplication. So there's some Ethicon documents on this USB, including IFUs. There are

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some PowerPoint presentations on TVT that have been shared with me or that I have given on behalf of Ethicon.
Q. Okay. Why don't we go ahead and mark that, then, Doctor, as Exhibit 5.
(Exhibit 5 was marked for identification.)
Q. (By Mr. Zonies) Anything else that you brought with you today, Doctor?
A. That's all I have.
Q. And in the binder that you have in front of you, Doctor, you said that there are -- how would you describe what's in the binder? Your report, and what else?
A. Okay. So starting at the beginning is the report, then there's a reliance list. It's labeled "MDL Wave 1," and that was printed March 2nd, 2016. And there's a list of expert reports at the end of that. Then there is a total of 74 tabs that have articles that I referenced in my report, so that's these two binders.
In addition to that, there's two bibliographies, one for the TVT general report that's listed in numeric order, and then the same list is there in alphabetical order.
Q. Anywhere in that binder, Doctor, are

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there materials that are not on your reliance list?
A. I don't believe so.
Q. So each of those tabs represents the footnote in your report and the materials that you referenced in that footnote in your report?
A. That's correct.
Q. Is it complete? In other words, does that have all of the material that would be referenced in a footnote in your report?
A. Yes. It has the first author's name. It has the title. It has the year and the page number.
Q. And for each of the tabs, if I asked you to turn to -- if tab 10, for example, or footnote 10 had three references, and you turned to footnote 10, would all three of those references necessarily be in those binders?
A. Well, each tab only has one reference, so we didn't put multiple references under one tab.
Q. Gotcha. So the tabs are just the items that you referenced in your report, but not multiple references for a single footnote, for example?
A. So if there was a single footnote, there may be a blank tab. So for example, 17 and 21 is

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the Ulmsteen reference, so it would only be in here once. It would be here under 17, but then when I hit the 21 tab, you know, that's blank.

Q. So for example, what is under tab 23? Or what would you have -- for footnote 23, how would you find those materials in those binders?

A. I see. So if I went to my report and my report says footnote 23, that's an Ethicon document, which is Bates number ETH-MESH9275943-45, then I go to my tab number 23, it has the same Bates number. And, you know, the article or the e-mail or the internal document, however you want to describe it, is there.

Q. And what do you have -- you see footnote 23 has a semicolon and then says "Axel Arnault deposition testimony"?

A. So that's what it says here under my reference. So in the body of the report, it says "TVT offered laser cut or mechanical cut, reference Number 23." You look down on the bottom of page 13, "Axel Arnault deposition," so when I go to 23, there's an e-mail there with respect to some internal communication.

Q. But there's nothing there that is Axel Arnault deposition testimony, correct?

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A. That's correct.

Q. And, in fact, you've never read Axel Arnault's deposition, have you?

A. I've never read it.

Q. So that citation in footnote 23 in your report where you're citing to Axel Arnault's deposition testimony, you've never actually red Axel Arnault's deposition testimony, correct?

A. That's correct.

Q. And so that's incorrect. You would change that in your report now?

A. Yeah, that could have been done better.

Q. Well, it could have been done truthfully, right? You've never read it.

MS. SCHMID: Objection; form, argumentative.

A. I've never read it.

Q. (By Mr. Zonies) Right. So in reality, that citation's incorrect, and you've never read that testimony, so that should be stricken from your report, correct?

MS. SCHMID: Objection; form, argumentative.

A. I've never read the report. I don't know the realities of whether it should be stricken or not stricken.

Q. (By Mr. Zonies) Well, did you actually

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cite to it? I don't know how it got in there if you've never read it.

A. I may have had some confusion when I was preparing the report, but as I mentioned earlier in the deposition, I have not read the report.

Q. And it's not on your reliance materials either, is it?

A. Well, the reliance list and the report may have some overlap, but I didn't take all the articles on the report and then duplicate them in the reliance list. The reliance list has articles that maybe weren't cited in the report.

Q. Now, according to your invoices, Doctor, you were finished with your -- this report, Exhibit 4, by the end of September of 2015, correct?

A. Correct.

Q. Did you make any modifications to that report between September of 2015 and February of 2016 when it was issued?

A. No substantive changes. So there may have been some grammatical errors or typographical errors that may have been changed, some formatting, but nothing regarding to the content.

Q. Subsequent to September of 2015 and

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before issuance of your report, did you come into possession of any new materials that would have impacted your report in any way, shape or form?

A. I don't believe so.

Q. You gave us a thumb drive which has been marked as Exhibit 5. On that thumb drive, you say there are additional Ethicon internal documents and some PowerPoints provided to you and copies of PowerPoints of presentations that you've given as well; is that correct?

A. Correct.

Q. Did you receive those materials subsequent to completing your report?

A. I don't believe so. I'd have to go back and take a look at that, but certainly, everything on there I've seen many times. The PowerPoints are quite old PowerPoints. And the IFU, certainly I've seen the IFU. You know, for more than ten years, I've read that, you know, as part of my practice, similar to the PowerPoints. Those are ones that I have given personally, many of them. So I'm very familiar with them. When I put them on the USB, or maybe I received a copy for convenience more recently, but these are things that I've received before.

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Q. Okay. The presentations that you've given that are on the thumb drive, do some of those presentations have to do with the TVT-Retropubic?
A. Yeah, I only put ones that were TVT-Retropubic. And the other depositions I try to separate the PowerPoints based on the product.
Q. You've had the opportunity to -- you were on the Ethicon speaker's bureau; is that right?
A. I was part of the speaking bureau, however you want to describe that. I was a consultant for Ethicon from 2004 to around 2011.
Q. And during that period of time, from 2004 to 2011, as a member of the speaker's bureau for Ethicon, you had the opportunity to give a number of talks about Ethicon's devices, correct?
A. Correct.
Q. And in giving those talks, sometimes you were provided the slide decks or the materials for the talk by Ethicon, correct?
A. Correct.
Q. And when Ethicon gave you those materials, generally, you were not permitted to alter those materials in any way, correct?
A. Correct.

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Q. And if you did make an alteration, it had to be approved by Ethicon, correct?
A. If it was going to be used at an Ethicon event.
Q. And do you believe that you gave any of those talks in 2011 using Ethicon's slide decks?
A. Not on that USB. That USB pertains to TVT-Retropubic. In 2011, any talks I would have given or projects I was involved in pertained to TVT-Exact and TVT-Abbrevo.
Q. When do you think, without -- I can open up the thumb drive. I'll do that on a break.
But do you have a sense of when the last time it was that you gave a talk using an Ethicon slide deck related to the TVT-Retropubic device?
A. Specific to the device, it would have been much earlier than that, probably around 2004 or 2005, but realizing as the new products came out, the TVT was always the predicate device, so many of the later talks, say, were on TVT-Exact, but there was a lot of slides that overlapped, slides that I had seen before. So we can answer that question a couple different ways.
In a 2011 presentation, there may have been a few slides that were used in earlier TVT-specific

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presentations, but now they're included in a TVT-Exact or TVT-Abbrevo, especially with regards to the mesh and the materials science. If it was the same mesh, then a lot of the slides were very similar.
Q. So certainly, in the time frame -- well, strike that.
When did you first start to use TVT-Exact?
A. TVT-Exact I started to use probably when it was launched, which I believe was around 2010 or 2011. I was part of the launch. I did go to Baltimore for the launch. There was a cadaver lab there, and then I did the first TVT-Exact case in Colorado.
Q. So in the 2010-2011 time frame, you had the opportunity to -- as a member of the Ethicon speaker's bureau, to give talks to physicians about the TVT-Exact device, and those talks would have included information about the TVT-Retropubic as well, correct?
A. That's correct.
Q. And you would have given those talks using Ethicon's preapproved slide deck; is that correct?
A. At Ethicon-approved events, yes.

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Q. And in addition to being on the speaker's bureau, you are acting today in a capacity as an expert witness for Ethicon; is that correct?
A. That's correct.
Q. And you have been acting as an expert witness for Ethicon in either a disclosed or a consulting capacity since when?
A. Probably sometime in around 2012.
Q. So since -- Doctor, I'll go ahead and hand you what I'm marking as Exhibit 6.
(Exhibit 6 was marked for identification.)
Q. (By Mr. Zonies) Doctor, Exhibit 6 is an e-mail from Brian Flynn to Jonathan Fernandez, dated December 19th, 2011; is that right?
A. Yes.
Q. This is an e-mail that you sent to an Ethicon employee in December of 2011, correct?
A. That's correct.
Q. Who is Jonathan Fernandez?
A. He was the professional education manager in the western United States. And he also was a former representative for Ethicon locally. So he -- I knew him in a number of different capacities.

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Q. You knew Mr. Fernandez first as your sales rep. He would come to your offices as a sales representative, correct?
A. That's correct.
Q. And then he moved his way into professional education at Ethicon, correct?
A. That's correct.
Q. And you continued to have a relationship with him in that capacity because he would work with you on professional education events, correct?
A. Correct.
Q. And in this e-mail to Mr. Fernandez, you write, "As of December 2011, all is well with me, although my practice is really changing from mesh kits to Biologicals, ASC and spending time trying to help defend J&J in a class action lawsuit versus Prolift PS." Did I read that correctly?
A. Yes.
Q. And is that what you were spending time doing in December of 2011?
A. Yes. I was getting -- at that point, I was having conversations with them in regards to these items.
Q. And so you testified that you believe you were first consulting as an expert sometime in

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2012. This seems fairly consistent with that, is that right, that in the end of 2011, beginning of 2012, you were consulting for Ethicon can as an expert?
A. That's correct.
Q. Did you think you started consulting with Ethicon as an expert shortly after or overlapping with when the last time that you acted as a consultant or a speaker on the speaker's bureau?
MS. SCHMID: Objection; form, vague.
A. I'm not certain, but pretty close in and around those dates.
Q. (By Mr. Zonies) You have testified previously that you were a consultant for Ethicon pretty much from 2004 through 2012, I think you've said before -- well, strike that.
So would it be fair to say that you first started consulting with Ethicon in or around 2004?
A. Yes.
Q. And that you consulted or worked on the speaker's bureau and also on the launch of a number of devices up and through sometime in 2011, correct?
A. Correct.

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Q. And then in 2011, you started working with Ethicon as a consultant on the litigations, correct?
A. Correct.
Q. And you continue to do that to this day, correct?
A. Correct.
Q. So you've effectively been a consultant working with Ethicon from 2004 all the way through today; is that fair?
MS. SCHMID: Objection; vague, compound. Go ahead.
A. Like I mentioned, I think 2004 to 2011, my consulting was directly with Ethicon as a speaker's bureau person and other capacities, and after '11 it was more surrounding the litigation.
Q. (By Mr. Zonies) In the next sentence you say, "Ultimately I suspect J&J will pay out millions." Is that what you wrote?
A. Yes, that's what I wrote.
Q. Was that your opinion at the time in 2011?
A. It may have been.
Q. Do you have a sense of why that was your opinion?

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A. When I was in New York City, I did a course there at NY University. I was asked to give a number of talks. And it just seemed like the medical-legal climate that was in New York was going to possibly spread to other parts of the country. And so this was after the FDA Public Health Notification, after the second one, and so certainly, there was a lot of talk that I would hear at meetings and other places about lawsuits and the potential for class-action lawsuits.
Q. Can you help us out and get them to do that, by the way?
A. Do what?
Q. Pay out millions.
A. That's not my role here.
MS. SCHMID: Objection; form. Go ahead. Next question.
MR. ZONIES: I thought I'd try, though.
Q. (By Mr. Zonies) When the Exact launched, the Exact allows a retropubic approach, correct?
A. Correct.
Q. Did you favor the Exact over the TVT-Retropubic?
A. Yes.

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Q. Why?
A. Mostly for ease of use. It allowed only one cystoscopy as opposed to two, so because of the new design with the plastic cannula, you were able to pass the trocar on both sides and then perform a single cystoscopy, where with the retropubic kit, you weren't able to do that because there was no cannula. There was just a metal trocar, and then there was a permanent device called the TVT Introducer that would get attached to the cannula -- to the trocar, and that could only be used on one side at a time.
So it was mostly because of that reason that I was able to do the case with performing one cystoscopy instead of two. Also, the TVT Introducer that was used to hold the trocar on the original kit, you know, sometimes was hard to locate. It wasn't something that J&J offered. It was a permanent tool that the hospitals would have, and operating out of a number of different ORs, I always felt more confident when I had everything in the kit compared to having to rely on some reusable instruments. So most surgeons for that reason preferred the TVT-Exact product.
Q. Did you find that because you only had

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to do one cystoscopy that your surgeries were shorter?
A. It would save approximately five to ten minutes.
Q. And that's a benefit to the patients, correct?
A. Yes.
Q. Did you have concerns when you had to use a reusable introducer that there were would be sterility issues?
A. No. No, it's the same as what you would experience with any reusable instrument or scissors or forceps, hemostats. We reuse overwhelmingly the majority of instruments we do in an operation.
Q. When you switched over to the TVT -- well, I guess my question is, did you -- when the Exact came out, did you switch over almost exclusively to the Exact as compared to the TVT-R?
A. For my retropubic cases, yes.
Q. So probably the last time you put in a TVT-R would be sometime in 2009 or 2010, whenever the Exact came to market?
A. Correct.
Q. So the last time that you've actually used the TVT-Retropubic device is approximately six

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years ago?
A. Sometime around 2010 or 2011 I think is when TVT-Exact came out, so whenever that date was.
Q. Is cystoscopy required when using the TVT-Retropubic?
A. It is.
Q. Are two cystoscopies required, in your opinion, when using the TVT-Retropubic device?
A. As many as you need to. Any time you have to repass the trocar or pass the trocar for the first time, what it recommends in the IFU is that a cystoscopy be performed.
Q. But in your opinion, it's not just a recommendation, it's necessary. It should be done, correct?
A. In my opinion, yes. And that's what I teach to my residents. That's what I do in my own practice.
Q. That's what should be in the IFU, right? It should say "cystoscopy is required"?
MS. SCHMID: Objection; form, argumentative, scope.
Go ahead.
A. I think that that is just part of basic fundamental surgical knowledge. With any

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antiincontinence procedure, once I'm done placing my sutures or my trocars, I perform cystoscopy. That's something that was taught to me as a resident, as a fellow, something I teach my students and residents.
Q. (By Mr. Zonies) And that's what should be in the IFU, that cystoscopy is required, correct?
MS. SCHMID: Objection; form, argumentative, scope.
A. I believe what the IFU recommends in regards to cystoscopy is adequate.
Q. (By Mr. Zonies) What does it recommend?
A. It recommends on the retropubic procedures that cystoscopy performed. On the obturator procedures, I believe that is listed as the discretion of the physician, so it's a stronger statement.
Q. And so my question is simply, Doctor, the IFU -- it sounds like you agree that the IFU should say, for TVT-Retropubic, cystoscopy is recommended or required, correct?
MS. SCHMID: Objection; form, argumentative, misstates prior testimony.
Go ahead.

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A. Yeah, I believe it misstates what I said. I said that that's part of the basic fundamental knowledge. I don't think you need the IFU to tell you that. After doing an antiincontinence procedure, I usually perform cystoscopy. Any time you're passing instruments next to the bladder, that's common knowledge. That's something that we do every day in our practice.

Q. (By Mr. Zonies) And you think that certainly Ethicon would understand that's common knowledge when they're selling a TVT-R, right? That cystoscopy should be done after the procedure, correct?

MS. SCHMID: Objection; form, foundation.

A. No, that's not correct. I think Ethicon has to assume that physicians are using reasonable judgment and care when using their products, but they're not going to tell the physician what antibiotic to use, how long to keep the Foley in, what kind of anesthesia they should use, what kind of dressing they should put on. So there's a lot of things in that procedure that Ethicon doesn't make recommendations on because that's part of our basic fundamental knowledge.

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Q. (By Mr. Zonies) So Doctor, if Ethicon knew that some physicians that it was selling the TVT-R to, if Ethicon knew that those physicians couldn't actually do a cystoscopy, or suspected it, and intentionally wrote the IFU such that cystoscopy was not required so that they could sell to those physicians, would that be okay in your mind?

MS. SCHMID: Objection; form, improper hypothetical, compound.

A. I can't answer that question the way that's stated.

Q. (By Mr. Zonies) Okay. Were you aware that Ethicon knew that some of the physicians to whom it was selling the device couldn't actually perform cystoscopy?

MS. SCHMID: Objection; foundation.

A. I'm not aware of that.

Q. (By Mr. Zonies) You've never seen any internal Ethicon documents discussing the concern that gynecologists don't know how to do cystoscopies?

MS. SCHMID: Same objection.

A. I'm not aware of that document. All of the gynecologists that I work with that perform

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antiincontinence surgeries know how to perform cystoscopy, so I'd be surprised that anybody would be doing antiincontinence surgery and do not know how to perform cystoscopy.

Q. (By Mr. Zonies) And if Ethicon knew that there were physicians who couldn't perform cystoscopy, and yet they sold a device to those physicians, is that okay, in your mind?

MS. SCHMID: Objection; form, vague.

A. I don't believe Ethicon sells the product to the physician. They sell it to the hospital, and then the hospital credentials the physician. The physician has to make a decision based on the privileges they request whether or not they're competent to do the procedure. So that's not really something that Ethicon is directly involved in. They sell it to the hospital, the hospital decides who's going to use it based on the credentials they provide.

Q. (By Mr. Zonies) Do you believe that Ethicon has any obligation whatsoever to include cystoscopy in the IFU?

MS. SCHMID: Objection; form, scope.

A. As I stated earlier, I don't believe that that's Ethicon's position.

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Q. (By Mr. Zonies) You don't think they have any responsibility to put that in?

A. I don't believe they have that responsibility.

Q. And as we discussed before, you don't know the FDA regulations that govern what should be in an IFU, correct?

MS. SCHMID: Objection; form, scope.

Go ahead.

A. In earlier depositions, and as I'll state now, I'm familiar with FDA requirements. I am by no means an expert in FDA regulatory, but I have reviewed documents, as I've cited earlier, about what is reasonable and what some expectations the FDA has when companies are creating IFUs, and then, you know, what the industry standards are for creating an IFU.

Q. (By Mr. Zonies) And what would you point to as your reliance for what the industry standards are when creating an IFU?

A. I would go back to the FDA documents. There's a blue book from, I think, 1993 where the FDA had come up with some recommendations. There's some other documents, I'm blanking on the author's name or the year, but FDA documents that I've

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reviewed most recently that I've mentioned in other testimonies that do give some recommendations on what should be included in the IFU.

Q. And have you ever reviewed Ethicon's internal standard operating procedures about what Ethicon believes should or should not be in an IFU?

A. I don't believe so.

Q. And Doctor, in your reliance materials, can you point me to the FDA materials that you're relying upon?

A. The FDA material that I'm relying on I believe I reviewed in preparation of another deposition, so I don't believe it's on the reliance list for this particular report.

Q. So Doctor, when do you believe you first started to use the TVT-Retropubic device?

A. Specific to the Ethicon product?

Q. Yes.

A. Sometime around 2004 or 2005 I started using the Ethicon products. The first product I used was TVT-Obturator. That was in 2004. Sometime after that I used the TVT classic device. And that's specific to my own practice. I started my practice in 2002 at the University of Colorado where I've practiced continuously since that time.

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I may have used the product earlier during my fellowship or residency, but I wasn't making the decisions about what products I was selecting. So I know, especially during my fellowship year, I had used a variety of products as my mentor at the time, George Webster, was trying various products to decide what he wanted to use in his practice.

Q. In your report, you recognize that you say that you first used the TVT-Retropubic in 1999. That's likely incorrect, isn't it?

A. Well, it would be incorrect if I included my residency. But if I include my own practice, then it would be incorrect. But I think when I wrote that report, it was in the context of part of my training.

Q. You don't have any specific recollection of using a TVT-Retropubic until 2005; is that fair?

A. No, that's not fair. What I had mentioned was -- the way I answered that question was, in my own practice, it started in 2002. In 1995, I started my residency. I started my urology years in 1997, so in 1998, I would have been a second-year resident. One of my mentors, Wen Yap, did a number of incontinence procedures, and I had used a variety of kits with him, biological

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products, autologous material, TVT, bone-anchored slings, biological slings. So I gained a lot of experience as a resident and a fellow, but when I wrote the report, I believe the way I wrote that was with respect to my own practice, so maybe that's why there's some discrepancy in the years.

Q. Because in your other reports, your TVT-Obturator report and the TVT-S report, you actually say that the first time you used a TVT-R was in 2001. Are you aware of that?

A. I'm not aware of that. What is confusing sometimes is the word "TVT" is often used interchangeably with "midurethral sling," so the TVT may have been stated, but it was really a Sparc or some other product. So I started using trocar-based polypropylene mesh slings as a resident. I didn't keep very close records as a resident and a fellow what products I used since I wasn't making the decision. You know, that wasn't something that was important to me then.

Q. So if you turn to page 22 of your report, Doctor, that's where it discusses when you began using these devices. Let me know when you're at page 22.

A. Yes.

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Q. You got that? Okay. And you say, "I had been using both the TVT-Obturator since 2004 and retropubic kits since 1999." That's what you wrote, correct?

A. Yes. And that's correct. So "retropubic kits" is just a generic term. That could include Sparc. That could include TVT. That could include Boston Scientific products. So that's any retropubic kit.

Q. And if I recall correctly from your earlier testimony, you know for sure that you started using TVT products in 2004 when you started to use the TVT-Obturator, correct?

MS. SCHMID: Objection; misstates prior testimony.

Go ahead.

A. What I know is that when I started in my practice, I used the American Medical Systems products from 2002 to 2004 at the University of Colorado and affiliated hospitals. And then in 2004 I switched from the American Medical Systems products to the Ethicon products, for the most part. There was exceptions based on what hospitals I practiced at, but that was a big switch. When TVT-Obturator became available, I was immediately

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attracted to that product.
Q. (By Mr. Zonies) Is it fair to say that from 2004 you had a preference for the obturator approach?
A. I had a preference for the obturator approach from 2004 to probably around 2008 or '9.
Q. And so why did you have a preference for the obturator approach as compared to the TVT-Retropubic?
A. A few reasons. One, there was less voiding dysfunction, so less urinary retention or bladder incomplete emptying. There was a lower risk of trocar injury to the bladder when placing the device. The procedure, at least in my hands, was slightly easier to perform as an outpatient with minimal anesthetic requirements. So those were the main reasons.
Q. So would it be fair to say that in that time frame, from 2004 until 2000 I think you said, '8 or '9, that the majority of your procedures were either using the TVT-Obturator device or, in those later years, the TVT-Secur?
A. I've always performed a variety of midurethral slings, but I always have had a preference. In addition to performing midurethral

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slings, I've always performed biological slings at the same time in my practice on different patients as well as bulking agents, artificial urinary sphincter. I tend to perform four or five different types of procedures for incontinence, but I always had a preference. And there was always one procedure that I would say that I did most frequently. So that was TVT-Obturator from 2004 'til TVT-Secur became available around 2008 or '9. Then I did mostly TVT-Secur. And then I switched doing mostly TVT-Abbrevo. And then at a later date, I migrated back to doing mostly retropubic.
Q. Using the TVT-Exact?
A. Correct.
Q. There was a certain period of time where you actually tracked the devices that you were using; is that right?
A. Yes.
Q. What was that period of time?
A. Since 2004, I've been tracking which devices I've been using until current.
Q. And do you have a sense from your data how many TVT-Retropubic devices you implanted between 2004 and today?
A. Just of the classic product?

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Q. Yes.
A. Somewhere around 75.
Q. And do you have a sense of, from the -- well, since you've been tracking which devices you've been using, is that spread pretty evenly over the years, or was there one or two years where you did most of those?
A. TVT classic was never the procedure I did most frequently. I generally reserved that for patients with more severe incontinence due to intrinsic sphincter deficiency. If you look at the medical literature and the Cochrane reviews, the Schmipff study, the TOMUS trial, there is a slight preference towards improved efficacy in patients with intrinsic sphincter deficiency with the retropubic approach when opposed to the transobturator approach. So there is slightly more risk with the retropubic approach in terms of voiding dysfunction and bladder perforation, so I tried to justify that risk when I had patients that had had more severe incontinence, maybe a prior failed procedure, et cetera.
Q. So the typical patient for whom you would have used a TVT-Retropubic device wouldn't have been the index patient. It would have been a

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patient with certain characteristics, such as ISD or a prior failed sling of some sort; is that fair?
A. For the most part. There were some exceptions where patients who were index patients that would receive the retropubic procedure, but that was unusual.
Q. Where did you and how did you come to the knowledge that the O had fewer risks than the R?
MS. SCHMID: Objection; foundation.
Go ahead.
A. That was based on some preliminary data that I had seen from Dr. De Leval's publications, and then from Dr. DeLorme, the outside-to-in approach. Generally, when you look at those obturator approaches, what we generically sometimes call TOTs, which include inside-out and outside-to-in procedures, it just seems obvious that you're going to be less likely to hit the bladder. I don't see any possibility where you would hit the intestine, less risk of major bleeding. So some of that was based on what the medical literature showed. Others was based on my medical training and education from doing dissections in cadaver labs. It's just a simpler

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space, the obturator space, than the retropubic space.
Q. So you said that you don't see any possibility where you would hit the intestine.
A. On a transobturator procedure.
Q. So one of the benefits of an obturator approach as compared to the TVT-Retropubic would be less risk of intestinal perforation and injury?
A. That's correct.
Q. And you also said less risk of major bleeding with the TVT-Obturator approach as compared to the retropubic, correct?
A. That's what I stated, yes.
Q. Bowel perforation is a very serious complication associated with the TVT-Retropubic; is that true?
MS. SCHMID: Objection; form, foundation.
A. Well, there's two statements there. I agree it is a serious complication, but it's rarely associated with a retropubic procedure. I think it would probably happen in less than 1/100th of the procedures. So I wouldn't say it's associated with the retropubic procedure.
Q. (By Mr. Zonies) And, I'm sorry, maybe I'm getting it wrong.

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When you said that one of the benefits of the TVT-Obturator as compared to the TVT-Retropubic is less risk of an intestinal injury, did you mean a bowel perforation?
A. Correct.
Q. Over the period of time where you did 75 total TVT-Retropubic surgeries, how many total surgeries did you do? In other words, what's the percentage?
A. Of -- percentage of what?
Q. Excellent question.
What's the percentage of midurethral slings that the TVT-Retropubic makes up? About one in ten, or fewer than that?
A. Well, as I've stated in my reports and other depositions, I've done 800 or so midurethral slings, of which 500 are Ethicon products. And in preparation of this deposition, I've looked at this recently, so I've done, I think, around 180 to 200 or so, hard to remember the exact number, TVT-Securs. That's the most common product I've used. I've done 140 or so obturator procedures, that would include TVT-O and TVT-Abbrevo as a group. I've done 75 of the TVT classic. I've done approximately 100 TVT-Exacts. And then there's

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other products that aren't TVTs that I've done, such as the Boston Scientific Advantage Fit, AMS Sparc, AMS BioArc, MiniArc.
So there's quite a few products there. But if you just look at the retropubic procedures alone, I've done over 200 retropubic procedures. So I don't know the exact breakdown of what that amounts to, Joe. I'd say at least 25 percent of my procedures have been retropubic procedures if you add up all the different products for retropubic products.
Q. And of those, it looks like about a quarter of those would have been TVT-Retropubic; is that fair?
A. A quarter?
Q. A quarter of your retropubic surgeries.
A. Well, if you just look at the Ethicon products, I've done 100 TVT-Exact and 75 TVT classic, so that's 175. The denominator of, say, if I did 800 slings, then that would be roughly a quarter of all midurethral slings.
Q. And if we take 75 TVT-Rs of your total of 800 procedures, it's less than 10 percent -- fewer than 10 percent of the surgeries that you've done with midurethral slings are TVT-Retropubic; is

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that fair?
A. Well, 80 into 800 would be 110, so less than one tenth.
Q. I can do that math.
A. Yeah, your math is getting better.
Q. And when do you think was the last time you used a TVT-Retropubic?
A. When TVT-Exact became available, so I think I stated earlier around 2011 or so.
Q. I'm going to mark Exhibit 7, Dr. Flynn.
(Exhibit 7 was marked for identification.)
Q. (By Mr. Zonies) Exhibit 7 is an e-mail from -- well, the first e-mail in the series is from Lori Campbell to Scott Jones, March 5th, 2004; do you see that?
A. Yes.
Q. And the subject is you, Dr. Brian Flynn, correct?
A. That's correct.
Q. In that e-mail -- who is Lori Campbell, first of all?
A. She is Scott Jones' boss.
Q. And Scott Jones is who?
A. He was a regional professional education manager in the western United States before John

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Fernandez and Lori Campbell was both of their bosses at different time points.

Q. And Ms. Campbell writes in the second paragraph -- well, first, Ms. Campbell writes, "Scott, we would like to expedite an offer to Dr. Flynn to become a local preceptor for Gynecare"; is that right?

A. Correct.

Q. And this is about when you first became a preceptor and started consulting with Ethicon in March of 2004; is that right?

A. That's right.

Q. And she writes in the second paragraph, "I am attaching the TVT Preceptor Recommendation Form. I understand you've observed his first TVT Gynemesh case this week and he is ready to convert the business. Congratulations." Is that what she wrote there?

A. Yes.

Q. And is that fairly consistent with your recollection that in your practice, the first time you used a TVT-Retropubic was around 2004?

A. As the attending physician, yes.

Q. And do you understand what it means when Ms. Campbell writes, "He is ready to convert the

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business"?

A. No, I am not --

MS. SCHMID: Objection; foundation.

A. It sounds like she's happy that I'm going to use her products, but I don't -- I can't say anything beyond that.

Q. (By Mr. Zonies) And she writes in the last sentence, "It sounds like he will be a wonderful asset to Gynecare and the Western region." Do you know what she means when she writes that?

MS. SCHMID: Objection; form, foundation.

A. I do.

Q. (By Mr. Zonies) What does she mean?

A. Well, I've largely been considered the key opinion leader in the western United States with reference to incontinence since the first day of my practice. One of the reasons I moved west is there wasn't a lot of experts in incontinence, especially in the state of Colorado. I was recruited here to start a practice in female pelvic medicine and reconstructive surgery. She knew I was a thought leader, that I educated residents and fellows. And a lot of other people in the state would be influenced based on what I did and what

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products I used. And I think because of my tremendous teaching skills, that she knew that I would be able to help educate physicians on their products.

Q. (By Mr. Zonies) And, in fact, that came true, right? You became a wonderful asset to Gynecare, correct?

A. I believe I provided a good service to Ethicon and Gynecare, and value to the company and their customers.

MS. SCHMID: Joe, when there's a time within the next couple of minutes, if we could take a quick break?

MR. ZONIES: Yeah, we can do it now.

MS. SCHMID: Is that okay?

MR. ZONIES: Sure.

MS. SCHMID: All right. Thank you.

THE WITNESS: Can we just finish this e-mail?

MS. SCHMID: Oh, my gosh, yes.

THE WITNESS: Let's just finish this thing.

Q. (By Mr. Zonies) You have more to say?

A. I don't, but I thought you probably did.

Q. No, I'm finished with the e-mail.

A. Okay. Very good.

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(Recess taken from 2:09 p.m. until 2:25 p.m.)

Q. (By Mr. Zonies) Doctor, are you ready to go after a break?

A. Yes, I am.

Q. Earlier, Doctor, we were talking about your speaker's bureau work with Ethicon. Do you remember those conversations?

A. Yes, I do.

Q. And that at some period of time, you were on the speaker's bureau for Ethicon, from roughly 2004 through 2011, correct?

A. Correct.

Q. And that during that period of time, you -- when you were asked to give a talk, would Ethicon compensate you for those talks?

A. Yes, they would.

Q. And would Ethicon sometimes pay for your travel to give those talks?

A. Yes. If I was already not there, if it was a meeting maybe I was attending, they would not, but if it was the only reason why I went there, then yes.

Q. And Ethicon would also pay for your meals during those trips; is that correct?

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A. That's correct.
Q. And you discussed that in some of those talks that you gave on the speaker's bureau that the materials would be provided to you by Ethicon, correct?
A. Correct.
Q. And that you weren't permitted to change those materials, correct?
A. Correct.
Q. Now, Doctor, you have been at the University of Colorado for most of your career; is that correct?
A. Yes.
Q. And at the University of Colorado, there are conflicts policies for physicians in your position, correct?
A. Correct.
Q. And were you aware that when you were giving these talks for Ethicon as part of the speaker's bureau that it violated the University of Colorado's conflicts policies?
MS. SCHMID: Objection; form, assuming facts not in evidence.
A. I was not aware of that.
Q. (By Mr. Zonies) So I'll mark what's

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Exhibit 8, which is entitled "A Policy to Limit Conflicts of Interest Between Healthcare Professionals and Industry Representatives for the University of Colorado."
(Exhibit 8 was marked for identification.)
Q. (By Mr. Zonies) Have you seen that policy before?
A. Yes, I have.
Q. And is this a policy that would have applied to you from 2008 forward?
A. I believe the policy went into effect around 2011.
Q. And there is, indeed, a 2012 policy, I think, that updates this policy. Were you aware that this 2008 policy existed prior to that?
MS. SCHMID: Objection; vague, foundation. Go ahead.
A. I was aware that the school was in the process of developing a policy that had gone through the faculty senate, and so it had gone through a number of iterations, and so I don't believe anything was set in stone until 2011.
Q. (By Mr. Zonies) The speaker's bureau that you were doing for Ethicon from 2004 through 2011, under the policy that you're speaking of, the

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2011 or 2012 policy, those speaker's bureau talks would have violated the new policy, correct?
MS. SCHMID: Objection; vague, compound.
A. I'm not going to agree to that, no.
Q. (By Mr. Zonies) And if you take a look at Exhibit 8, Doctor, and you turn to page 6, there's a section called "Participation on speakers bureaus"; do you see that?
A. I do.
Q. And it says, "Speakers bureaus, which are often 'little more than extensions of a company's marketing department' may pose real or perceived conflicts of interest." Do you agree with that statement?
A. No, I do not.
Q. And "HSC," it says. And that's your employer, correct, HSC?
A. "Health science centers" is a generic term. This contract's one that all the schools have. So this contract I don't believe is written specific for the University of Colorado, so when they say HSC, health science center, that's not University of Colorado, that's not University Physicians, Inc. HSC is health science center.
Q. But this policy would apply to you,

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correct?
A. I don't believe this policy applied to me, no.
Q. And let me clarify that. That's because you didn't think that this was a -- you don't believe, as you sit here today, that this policy was in effect as of 2008; is that correct?
A. There's a variety of reasons why I didn't think it was applicable, and so I believe that this was written primarily as it pertains to relationships with pharma, and not medical device companies. Speaking bureau, I don't think that's an accurate description on what I was doing for Ethicon. That's not what I considered my role there. So there's a lot of exceptions to this policy.
Q. Okay. And so if you turn to page 2, where it says "Background," do you have that section?
A. Yes.
Q. And the third sentence, it says -- it's discussing use of drugs and medical devices, right? So this clearly applies to medical devices, correct? Third line down.
A. Yeah, I see that. It's not saying it

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applies to them. This is just background information, an introduction paragraph.

Q. And then if you look at "Scope of Policy," it says, "This policy applies" -- on the bottom of that page, "This policy applies to all health sciences students, residents and other trainees, and to all regular faculty members at the University of Colorado Denver Schools of Dental Medicine, Medicine, Nursing, public Health and Pharmacy. Health sciences library faculty are also covered by this policy. The term 'health science students, residents and faculty' is used to describe all these parties in an inclusive manner." Would that include you?

A. Well, I am a faculty member, so . . .

Q. So yes, that would include you?

A. Yes.

Q. If you turn to where we were, page 6, about participation on speakers' bureaus, the second sentence says, "HSC students, residents and faculty," we've determined that includes you, correct?

A. Correct.

Q. "HSC faculty may not participate in or receive compensation for talks through a speakers

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bureau if, A, the content of the lectures, slides, references or educational handouts is subject to approval by industry representatives."

First, did I read that correctly?

A. Yes, you read it correctly.

Q. And you've testified that the content of the slides that you presented on as a member of Ethicon's speaker's bureau, that the content of those slides was written by Ethicon and you weren't permitted to change it, correct?

A. Correct.

Q. So if this policy were in place, you violated this policy, correct?

MS. SCHMID: Objection; form, assuming facts not in evidence, calls for a legal conclusion.

A. First of all, it was not in place. Second of all, I don't believe I violated it.

Q. (By Mr. Zonies) And which portion -- I understand you don't believe this was in place, so my questions will be based on an assumption that it was in place.

So assuming this were in place, where do you think you didn't violate this section I just read?

MS. SCHMID: Same objections.

Go ahead.

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A. A speaker's bureau is a commonly recognized term that is related to pharmaceutical industry where you go out and give dinner talks, et cetera, on behalf of the company and you use the company slides. What I did is very different than that. My primary role in the consulting with Ethicon was being part of the innovation council, doing cadaver labs, doing preceptorships and proctorships. Those were the roles. The slide deck and the talks, that really wasn't my role. That was something that was generally performed by other consultants more senior than me. So typically, when I attended a course or when I participated in a course, I was the person doing more the instruction during the cadaver lab portion and then doing the preceptorships and proctorships.

The dinner talks and the prof ed -- you know, the dinner programs as you're referring to, I think that's what this policy is referring to. That's really not what I did.

Q. But we've established that you used their slide decks to give talks, correct? It may not have been most of what you did, but you have done that, correct?

A. I've used them as part of preceptorships

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and proctorships. You know, I've had them in my possession. I've used them to educate myself and residents, but no, I wasn't -- I wasn't part of the speaker's bureau. There was no speaker's bureau that really existed. That's not -- you can read that e-mail that we looked at earlier. And I don't think the word "speaker's bureau" is ever even mentioned in Exhibit 7. It says, "Dr. Flynn to become a local preceptor for Gynecare." It doesn't say Dr. Flynn's going to enter our speaker bureau. "In addition, we'd like to invite him to the preceptor summit." So the whole idea of being a preceptor or being a proctor was try to help educate people on the surgical procedures. As a surgeon, that's what I did.

Q. So earlier -- and just to be clear, earlier you testified you were on the speaker's bureau for Ethicon and your testimony now is that you were not on the speaker's bureau for Ethicon?

A. What my testimony was earlier and now is that I was a consultant from 2004 to 2011. That's what I've stated multiple times. And you characterized me as being on the speaker's bureau. That's not a characterization that I've used or that I've seen Ethicon use in any of their e-mails

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or in the consulting agreement that I submitted earlier. We can go back and look at the consulting agreement and see what terms are on there, but I don't believe the word "speaker's bureau" is on the title of that contract.

Q. Do you think "speaker's bureau" is in the contract?

A. It may be in there, but it itemizes all the different activities a consultant can do. And what I mentioned is my activities were preceptoring and proctoring, developing videos and content. That's primarily what my role was.

Q. The next paragraph down says, "All speaking relationships and contracts are subject to review and approval by the university."

Did you ever submit your contracts to the university for their approval and review?

A. Yes.

Q. When did you do that?

A. I don't recall.

Q. Did you ever accept pens, note pads, mugs, pen lights, calipers, textbooks, free or discounted tickets to sporting events from Ethicon?

A. No.

Q. You never took an Ethicon pen?

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A. No.

Q. Did you ever -- we've discussed that you -- Ethicon would sometimes purchase meals for you when you were traveling; is that right?

A. Yes.

Q. And some of these were for Ethicon, I think you described them as Ethicon talks; is that right? Not professional-society talks.

A. These were industry sponsored events that Ethicon was the sponsor primarily. There were sometimes joint events, but for the most part, they were the only sponsor.

Q. They weren't, for example -- you gave these talks sometimes at an Ethicon-sponsored event that wasn't tied to AUGS or SUFU or some professional society, correct?

A. Correct.

Q. So if you turn to page 4 of the policy, you'll see "Gifts and Meals"; do you see that?

A. I do.

Q. And it says that, number 3, "Meals, beverages, snacks or other hospitality paid for by industry or industry representatives shall not be provided to or accepted by HSC students, residents or faculty."

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First, did I read that correctly?

A. Yes.

Q. And that policy, if it were in effect, would apply to you, correct?

MS. SCHMID: Objection; foundation, assumes facts not in evidence.

A. Yes.

Q. (By Mr. Zonies) And so by accepting meals, beverages and other hospitality, for example, Ethicon would pay for your hotel rooms and travel, correct?

A. Correct.

Q. You would have violated this policy if it were in effect, correct?

A. Not correct.

Q. Why not?

A. I can't violate a policy that's not in effect. I mean, that's -- it's completely hypothetical. And this policy was not approved by the faculty senate. This is a policy that was proposed. What you put in front of me in 2008 was never approved. So of course nobody adhered to rules that didn't exist. This is completely hypothetical. And so, I mean, this whole line of questioning is really ridiculous.

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Q. So when this policy was proposed, were you part of working on this policy?

A. No, I wasn't on the faculty senate.

Q. Did you attend any of the discussions about what should or shouldn't be in the policy?

A. I provided feedback to my representative, but I wasn't at the actual meetings or any of the votes.

Q. And who was your representative?

A. One of my partners.

Q. Who was that?

A. Shandra Wilson.

Q. And you provided feedback on -- do you recall what type of feedback you provided?

A. Just that I disagreed with a number of the items in this policy. I thought it was overreaching and was not legally valid. You can't prohibit someone from doing what they want to do on their free time as their employer. And I think that's been adjudicated in different venues. But if someone's on their free time, if it's the weekend, the employer has no right to dictate what the employee should do with their free time. So all of these things that I did were on my own time, either on vacation time, at night, or on the

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weekends. And for that reason, that's why this policy didn't get approved in this form, because the overwhelming majority of the faculty did not agree or wanted to abide by something that, you know, was so overreaching.

Q. And do you feel that it's important for you when you publish a paper to disclose that you were or are a consultant for a medical device company?

MS. SCHMID: Objection; vague.

Go ahead.

A. I adhere to what the publication requests. So what most publications ask is that if the publication pertains to a particular product that you're writing about, and you're a consultant that's active at the time, then yes. So there's a lot of caveats to that statement. But I'm familiar with the various, you know, requests from the various journals.

Q. (By Mr. Zonies) So you published a paper in 2013 in the International Urogynecology Journal, correct?

A. Correct.

Q. And in that 2013 publication, during the time when this paper was written and then

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published, you were acting as an expert consultant for Ethicon in this litigation, correct?

A. I wouldn't agree with that, no.

Q. You weren't acting as an expert for Ethicon in 2013?

A. I was doing consulting work at the request of Butler and Snow. I wasn't employed by Ethicon. I wasn't directly paid by Ethicon, so that's one reason why I didn't disclose that.

Number two, I don't believe the article really had anything to do specific to a product. That article pertains to a number of products that we listed. And, in fact, I'm not aware of any other article that had listed all of the products the way I did in Table 2 or 3 in that article. When you compare that to other articles, I think that we were transparent in which products were removed.

Q. Correct. And in this article, in fact, Table 2, good memory, you specifically list Ethicon's TVT as one of the devices that you are writing about in this article, correct?

A. Correct.

Q. And at this time, you were engaged as an expert witness by Ethicon's lawyers to testify and

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be an expert in Ethicon TVT litigation, correct?

A. I don't agree with that, no.

Q. And you certainly didn't disclose that you were an expert witness in the Ethicon TVT litigation in this article, did you?

A. What I'll say is I'm not aware of a single author ever that's ever disclosed in any article expert witness work, not Dr. Ostergard, not Dr. Elliot, not Jerry Blaivas, not Dr. Rosenzweig, not Dr. Margolis. So that's not a standard that anybody adheres to. The consulting relationships and what's offered in the disclosures are related to pharma and medical device companies. No one that I'm aware of -- maybe you can show me an article where someone's ever disclosed medical-legal consulting work as a conflict of interest, even in articles that pertain to medical-legal work.

Q. So is it your testimony, as you sit here today, that if you publish an article in a peer-reviewed paper about the TVT-Retropubic device, you would not disclose that you're an expert witness working on the Ethicon litigation?

A. That's correct.

Q. One of your opinions about the TVT mesh

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that's used in the TVT and the TVT-O and S and Exact and Abbrevo is that you don't believe that it degrades; is that correct?

A. That's correct.

Q. And first of all, what does "degrade" mean to you, in your expert opinion?

A. Well, usually, when I think of degradation, I think of it often at a macroscopic level, so seeing gross breaks or cracks, fragmentation of a product.

Q. And it's page 27 in your report if you wanted to turn to it. I'm sorry to interrupt. Go ahead.

A. So that's what I consider for gross or macroscopic degradation. There are papers in the literature that cite to SEM, which is electron microscopy showing microscopic cracking, and so people think of it both grossly and microscopically.

Q. And is it your expert opinion that there's no evidence of degradation grossly?

A. To the patients that I've operated on for, say, recurrent incontinence or for other indications, I haven't seen gross evidence of degradation on my reoperations.

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Q. So is it fair to say that your opinion that there is no degradation associated with polypropylene is limited to grossly?

A. In my own clinical practice, yes, because I have not looked at any of these specimens personally under electron microscopy of explants that I've performed, but I am familiar with Dr. Clave's article and Dr. Costello's article and other articles that reference degradation, so I have read those articles as part of my practice, in journal clubs, et cetera. I've seen those articles be brought up at meetings. Recently I had attended a meeting of IUGA, International Urogynecologic Association, I saw Dr. Ostergard present what he considered evidence of degradation at this mock trial that occurred at the IUGA meeting.

Q. A mock trial occurred?

A. A mock trial, yes. And so --

Q. Who was the lawyer?

A. I think Ostergard was the expert and the attorney. So nonetheless, there's articles that I'm familiar with and I am confident in my opinions that degradation does not occur with polypropylene mesh, either microscopic or macroscopic.

Q. Okay. So let's talk about the -- I

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think we've concluded that you believe -- it's your expert opinion that degradation of polypropylene mesh does not occur macroscopically, correct?

A. Correct.

Q. And that is based on your personal clinical experience; is that correct?

A. My own experience, that of others, and that's what's reported in the medical literature, in the Cochrane reviews, the systematic reviews by Schmipff and by others over 20 years of TVT implants. I believe that we would have more evidence that would exist of degradation if it truly, in fact, did exist when you consider the large number of patients that have been implanted over the last 20 years.

Q. So let me test that. I want to make sure I understand all the bases for your opinion.

So your opinion is that you do not believe that polypropylene mesh, as used in the Ethicon devices, degrades over time when it's in the body. And your support for that is your own personal practice, and also the systematic reviews, such as Cochrane. Anything else.

MS. SCHMID: Objection; misstates prior testimony.

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Go ahead.

A. And also my review of the Clave paper and the Costello paper. And there's other papers like that that are more editorials on these two papers. So I didn't cite them separately, but Dr. Ostergard has written commentary on the Clave paper. Howard Goldman has written commentary on the Costello paper and the Clave paper. So I feel comfortable with my opinions based on reviewing the figures in those papers and the examples of the electron microscopy, and then my own clinical experience and my review of the medical literature.

Q. Okay. So let's talk about microscopic degradation, okay?

A. Yes.

Q. What do you rely upon for your opinion that polypropylene mesh as used in Ethicon's devices does not degrade at the microscopic level?

A. What do I rely on?

Q. Yes.

A. Well, I believe, like you would see, say, for instance, a bacterial infection, so though we don't see the bacteria and we don't see the macrophages, we see the effects that they cause, like purulence or pus. If you were having

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microscopic degradation, you would expect to have some consequences of that, for instance, like free radicals, peroxides and other things being released into your system, and there's no evidence to support that. So when people look at peroxide levels and other toxic metabolites that would result from degradation or from oxidation, there's nothing to report that in any of the medical literature. I've never witnessed that in any of my patients. If microscopic degradation continued to exist, you'd expect to eventually see gross evidence of that.

So there's a lot of things that we can't see on the microscopic level because it's hard to detect, but once it reaches the gross level, you should be able to see that. And you should be able to understand that it began at a microscopic level, and now you're just seeing the gross evidence of that.

So I think I could infer from my gross observations of what's happening microscopically and then based on the reports and these articles that I've reviewed. I just don't see the evidence.

Q. So you understand that the reports that you cite, Clave and Costello and others, actually

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using SEM demonstrate degradation, correct?
MS. SCHMID: Objection; foundation.
A. I believe that's what they report in their conclusions, but I have problems with their methods. And I think that their products in their papers include Bard products. They include heavyweight meshes. They include patients that have had multiple meshes inserted. The Costello paper's about hernia literature. It doesn't even pertain to transvaginal mesh explants.
The Clave paper takes about six different subgroups and lumps them all into one big group and then asks you to make conclusions. So they have some patients in that study that didn't even have polypropylene inserted; they had polyester and other products. And so it's very difficult to understand their conclusions.
And, to me, it almost seems like an intentional attempt at confusing the reader when you have so many products and then you draw conclusions based on all of these products in their summary statements. So I don't believe that the evidence exists in those papers.
Q. And if a paper were published that solved some of those concerns of yours about the

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methods, is that something that you'd want to review and include in your expert opinion?
A. I'd be happy to review the paper if I thought that the paper was valuable or something that I should include in my report, I would, but I can't say that without looking at the particular paper.
Q. Now, you have a list of depositions at the end of your reliance materials, and I noted that -- I'm sorry, a list of expert reports that you reviewed at the end of your reliance materials, correct?
A. Yeah, there is a list of a number of expert reports.
Q. And I notice that, for example, plaintiffs' experts who are the pathologists that discuss degradation, you didn't review any of those expert reports, did you?
A. Not in very much detail, so for that reason, I didn't put them on my reliance list.
Q. You've never reviewed any deposition testimony or expert reports of Dr. Klinge, for example?
A. Yeah, I've read a number of his papers, but I don't believe I've ever read his expert

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report.
Q. Or Dr. Klosterhalfen?
A. Similarly. I think he's on some of the same publications with Dr. Klinge supporting a PVDF product, which I believe they endorse over polypropylene, but I don't believe I reviewed their expert reports.
Q. Or Dr. Jordi Muehl?
A. I am not familiar with that doctor's publications or expert opinions.
Q. And you've never yourself performed any analysis of explanted meshes to determine whether or not there was degradation, have you?
A. I've looked at my explants grossly. I've taken measurements. The pathology department at university takes pictures. They preserve the specimens at the request of the plaintiffs' attorneys, but I have not personally done any SEM or chemical analysis or FTIR analysis of the meshes.
Q. And you know, or I think you've testified before, that your pathology department doesn't even look for degradation, so you wouldn't know if it exists or not on your explanted meshes, correct?

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A. They do report if there would be gross degradation, so on their gross report, they'll make measurements, and they'll provide information on what the explant looked like. So if there was cracking or breaking or fragmentation, I would expect to see that in the report.
Q. Have you ever reviewed any of Dr. Iakovlev's articles?
A. I am familiar with the name, but I can't cite to their reference or his expert reports, but I know that he's either a materials scientist or a pathologist.
Q. Would you defer to his analysis of the explanted meshes when he's discussing the microscopic evidence of degradation?
MS. SCHMID: Objection; foundation.
A. No, I would not.
Q. (By Mr. Zonies) Do you think you're better qualified than he?
A. No, but he has been hired by plaintiffs' experts to be an expert. Similarly, Ethicon has pathologists and materials scientists that are their experts, so in my testimony, I'm prepared to make comments on what I see clinically. I'm prepared to comment on these papers that I had

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mentioned. I'm prepared to comment what systematic reviews report, but I'm not going to make comments or opinions on SEMs or how they're performed or my own personal experience in performing SEMs.

Q. So I notice Dr. Iakovlev's -- none of his papers are on your reliance materials, correct?

A. Correct.

Q. I'm going to hand you what's been marked as Exhibit 9, a paper from Dr. Iakovlev entitled "Degradation of polypropylene in vivo: A microscopic analysis of meshes explanted from patients."

(Exhibit 9 was marked for identification.)

Q. (By Mr. Zonies) You've never seen this article before, correct?

A. I don't believe so.

Q. And we can start, Doctor, if you'd like, by looking on page 11 where the authors actually do a disclosure. You asked for evidence that anyone would do this, and I'll turn your attention to page 11. Are you with me?

A. Yes.

Q. Do you see where it says "Acknowledgements"?

A. I do.

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Q. And can you read that sentence out loud to me?

A. It says, "Authors provide expert opinions for medical-legal cases on matters related to polypropylene mesh."

Q. Is that something you think you should now do when you publish articles, is disclose your conflict?

A. I think it would, again, depend on the standards of the journal. So I've never published in this journal, Biomaterials and Research. It's not a journal that I subscribe to or read. This looks like this is an engineering journal, so their requirements may be different than what's in the medical journals.

Q. On page 27 of your report, you say, and I'm quoting, "Moreover" --

MS. SCHMID: I'm sorry. Let me just -- one moment, please.

MR. ZONIES: Sure. Page 27.

MS. SCHMID: Thank you.

Q. (By Mr. Zonies) Let me know when you're there, Doc.

A. Yes.

Q. On page 27, the last sentence,

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"Moreover, I have never read or seen a single peer-reviewed published article or seen any cited by plaintiffs' experts that showed any clinical effect of degradation."

If such an article existed, you'd like to see that, right?

A. I would read that article, sure.

Q. Okay. So I've handed you Exhibit 9, Doctor. And if you turn to Dr. Iakovlev's article entitled "Degradation of polypropylene in vivo" and you look at the abstract on the first page -- are you with me?

A. Yes.

Q. And he says in the second column here, "Several features indicated that the degradation layer formed in vivo: inflammatory cells trapped within fissures, melting caused by cautery of excision surgery, and gradual but progressive growth of the degradation layer while in the body"; do you see that?

A. I do.

Q. Do you have any evidence whatsoever that this is incorrect, wrong, unreliable or in any way wrong?

MS. SCHMID: Objection; form, foundation.

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This witness was just handed a 12-page paper that he's already testified he's never seen before, so . . .

Q. (By Mr. Zonies) Well, the next sentence says, Doctor, "Cracking of the degraded material contributed to a clinically important mesh stiffening and deformation." Is that what they concluded there?

MS. SCHMID: Same objections.

A. I can't comment on what their conclusions are. I can immediately point out that it says "melting caused by cautery of the excision surgery." So what that suggests to me is that the excision surgery caused cracking and fissures and melting of the mesh, so I'm not sure why that would be evidence of degradation if your cautery injured the mesh.

Q. (By Mr. Zonies) The conclusion, Doctor, is "Cracking of the degraded material indicated a contribution to clinically important mesh stiffening and deformation."

And my question is, if that's what this paper demonstrates, wouldn't that be pretty important for you to know before you gave your expert opinion in this case?

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MS. SCHMID: Objection; foundation, assuming facts not in evidence.
A. My answer to that would be no.
Q. (By Mr. Zonies) You wouldn't want to read this before giving your expert opinion?
A. I believe I've read enough articles on degradation. I've read enough systematic reviews and meta-analyses to feel confident in my opinions.
Q. Can you tell me one systematic review or meta-analysis that discusses the degradation of polypropylene?
A. I think the systematic reviews and meta-analyses do a good job in reviewing and recording and tabulating complications. So if you're considering degradation a complication, I would expect to see that in the systematic review.
Q. You believe that the systematic review of -- for example, the Cochrane review, do you believe that was a review of whether or not polypropylene mesh degrades?
A. It's a review of the outcomes of polypropylene mesh. And if degradation is a potential outcome that you're citing, then I would expect to see that in the review, yes.
Q. If you turn to page 4 -- well, you've

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never read this study before; is that right, Doctor?
A. That's correct.
Q. All right. So I'm not going to take you through this study and point out things that you haven't read. I do think that that wouldn't be a good use of our time here.
Would you agree, Doctor, that if polypropylene mesh degraded even at the microscopic level, that it would increase the potential for bacterial colonization in the mesh?
MS. SCHMID: Objection; foundation, vague, improper hypothetical.
A. I'm uncertain on what the implications of the cracking would be.
Q. (By Mr. Zonies) You don't know one way or the other?
A. I don't know one way or another. I haven't read any reports on what the implications of cracking would be, or I'm not aware of any papers that show bacteria inside these cracks, but . . .
Q. And again, you've never read this paper?
A. I have not read this paper.
Q. And you've actually done some work on

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bacterial -- bacteria and meshes, correct?
A. Correct.
Q. Can you describe that work for me, please?
A. We had a paper at the American Urologic Association meeting, in the abstract and poster form, looking at bacterial analysis of explanted meshes. We looked at a number of groups, including patients that had what we considered painful mesh, which is an IUGA Type I, pain without any exposure or perforation. Then we looked at patients that had IUGA II and III as a group, that would be people that had exposed mesh, also known as extruded mesh, and then another group of patients that had mesh perforated into the lower urinary tract, that would be IUGA IV. And then we also had what we would consider our control group which were people that were having revisions more for recurrent incontinence or for other indications unrelated to pain, exposure or perforation.
Q. And what was the conclusion of your study?
A. I would have to look at the study again, if you want to read the exact conclusion. We never published the study. The paper received a lot of

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criticism because of the methods, and so it wasn't something that we pursued.
Q. Wasn't one of the conclusions that in 80 percent of the explanted meshes where it was explanted for pain, exposure or perforation, that there was bacterial pathogens?
MS. SCHMID: Objection; form.
A. I would have to look at the abstract again. The goal of the paper was to try to help identify, you know, why patients might have pain unrelated to exposure or perforation.
Q. (By Mr. Zonies) And you've described that before. You've expressed that you have a particular interest or a theory that you were working on related to infection, mesh infections and pain; is that right?
A. I think that overstates what the work was. Dr. Shaw, who was my fellow, was curious about this, and it was something that we had worked on together.
Q. I'll go ahead and mark as Exhibit 10 your abstract.
(Exhibit 10 was marked for identification.)
Q. (By Mr. Zonies) Is Exhibit 10, entitled "Bacteriological Analysis of Explanted Transvaginal

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Meshes," the abstract we were just talking about?
A. Yes.
Q. And your conclusion that you reached in this abstract is, "Colonization of vaginally implanted mesh occurs frequently, and bacterial infection may account for pelvic pain in patients with painful mesh and dyspareunia." Is that what you concluded in this abstract?
A. That's what we concluded in the abstract.
Q. And you also, in your chart, you actually reflect that in those patients where what you called your control patients, that none of them had pathogenic organisms; is that correct?
A. That's correct, but we only had four patients in that group, so there's no P values in any of these charts. We couldn't reach statistical significance because the numbers were so small in this study.
Q. And you also find there that 83 percent of those women who had a urinary tract erosion had pathogenic organisms, correct?
A. Correct.
Q. And your conclusion right above that was that the bacterial infection that you found in

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these explanted meshes may account for pelvic pain in patients with painful mesh and dyspareunia, correct?
A. And what we said is it may account. It didn't say it did account. What was probably most surprising, if you look at our vaginal erosion patients, I think that there's a thought that a hundred percent of those patients have mesh that's colonized with bacteria and only 20 percent of the patients had pathologic organisms in that exposed mesh, so 80 percent did not. And so this was sort of a pilot study. The results weren't really what we expected. And so we're still working through how to interpret this data.
Q. So tell me how you're doing that work.
A. We continue to send culture information on our explants for microbiologic analysis both for aerobic and anaerobic cultures. We send for pathological analysis, as we mentioned earlier. I haven't collected the data in an organized form since this abstract, but if I get that report back from the pathology lab, and I'll have to sign off on all those reports, on all the outcomes, so I look at those reports as they come to me.
Q. So you have that data available to you?

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A. I don't have it collected. You know, I mentioned in this group of 50 patients, we had that data available to us in 2013. But since that time, I'm only looking at it on a case-by-case as I get reports from my microbiology lab, but I haven't tabulated it since 2013.
Q. So we have no way to see what your current data shows?
A. We don't.
MR. ZONIES: Why don't we go ahead and take a break.
MS. SCHMID: Sure.
(Recess taken from 3:14 p.m. until 3:38 p.m.)
Q. (By Mr. Zonies) Doctor, we're back from a break. Are you ready to go?
A. Yes, I'm ready to go.
(Exhibit 11 was marked for identification.)
Q. I'm going to hand you what's been marked as Exhibit 11. Exhibit 11 is a study by Tzartzeva entitled "In-Depth Nano-Investigation of Vaginal Mesh and Tape Fiber Explants in Women."
I notice this abstract was not on your reliance materials, correct?
A. Correct.

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Q. You've never reviewed that paper before either, have you?
A. I don't believe so.
Q. In fact, Doctor, these studies that I think you mentioned, studies that do these SEM images from explant samples, you don't find those studies particularly informative; is that right?
A. That's not what I stated. I did cite to the Clave paper which has plenty of SEM samples in it.
Q. And do you have any -- if you see in the middle of this Exhibit 11 that I just handed to you in the "Results" section -- are you with me? It's the sentence that starts with "Comparison."
A. Yes.
Q. "Comparison of the SEM images from explant samples with controlled pristine samples revealed extensive surface degradation with formation of microscopic surface cracks of several microns in length and depth."
Is that what this study found in the results?
A. That's what you just read to me. That's what's written here. I can't comment beyond that. I'm not familiar with this study, and I don't know

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what the pristine control group is comprised of. I don't even know what the explant is, what kind of polypropylene mesh explant this was.

Q. And if you flip it over on the back of it, it actually shows you that this is comparing a Gynemesh, and Figure 3 is TVT mesh, correct?

MS. SCHMID: Objection; foundation.

A. TVT and Sparc.

Q. (By Mr. Zonies) Right. And it says "TVT" -- or pictures A and B comparing the explanted mesh in A to B, the pristine mesh. Do you -- just grossly looking at those pictures, do you notice a difference?

MS. SCHMID: Objection; foundation, scope.

A. Well, these are microscopic images, so it's hard for me to comment grossly on a microscopic image, but I'm not going to comment because I just don't know enough about that photograph to make an intelligent comment about it.

Q. (By Mr. Zonies) And that's because you've never reviewed that paper, correct?

A. Correct.

Q. One of the papers you did review in your -- I believe is on your reliance, is a paper by Moalli. Do you recall that paper?

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A. I've reviewed a number of her papers.

(Exhibit 12 was marked for identification.)

Q. (By Mr. Zonies) And I'm going to hand you what's been marked as Exhibit 12. Do you have any criticisms of Exhibit 12, the Moalli paper entitled "Tensile properties of five commonly used mid-urethral slings relative to the TVT"?

A. The paper is well done, for the most part, but there are some limitations of the paper. I wouldn't necessarily call them criticisms, but there are limitations to studies that are done ex vivo, what we call a dry lab, you know, on a stretch rack. I don't know if these studies are necessarily representative of what occurs in vivo.

Also, I have concerns when the entire 45 centimeters of the mesh is not tested. Oftentimes, these meshes, for instance in this study, were cut in 8-centimeter samples, so how a mesh that's 8 centimeters behaves, you know, doesn't necessarily represent the 45-centimeter mesh that is TVT or maybe what ordinarily ends up in the body, probably around 20 to 25 centimeters. So those are some obvious limitations.

Also, they don't account for tissue ingrowth and how tissue ingrowth may resist some of the

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effects of stretching and cycling of the meshes. But I am happy to comment on this paper. I am familiar with this paper. It is in my reliance list.

Q. You mentioned cycling. Can you explain to me what you meant when you said that?

A. Cycle, at least in terms of biomechanical terms, is stretching the mesh and then relaxing the mesh, stretching the mesh then relaxing the mesh. So if you look at Figure 1, it shows how that's done in Dr. Moalli's laboratory. And then if you look at Figure 2, it shows some of the meshes after they've undergone cycling. And then in Figure 3 and especially Figure 5, Figure 5 shows probably the best example of cycling of a mesh ex vivo.

Q. And do you believe that in vivo mesh is -- goes through cycles?

A. Yeah, I think that's one of the ideal characteristics of the TVT mesh, is that it bends, but it doesn't break, and so you want a mesh that's going to be elongated or be elastic when undergoing effort stresses.

Q. And when you said Figure 5 showing the cycling, do you have any reason to dispute the

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conclusions that are reached in Figure 5?

A. It says, "With each cycle, the peaks and valleys of the curve move progressively to the right of the graft indicating permanent (nonreversible) elongation." I agree with that conclusion with respect to the dry-lab testing. And I think that that's something that Dr. Moalli's reported on. Whether or not this is what occurs in vivo after tissue ingrowth, if they're speculating that that occurs, then I think that would be an overreach on their conclusion.

Q. Do you believe that a 20 percent elongation is an approximation of how meshes react that you have implanted?

MS. SCHMID: Objection; foundation, scope. Go ahead.

A. I think typical elongations that I'm more familiar with, for instance what's reported in other papers, is around 3 to 5 percent, not the 20 to 60 percent relative elongation. So elongation's going to depend a lot on how many cycles. It's going to depend on tissue ingrowth. It's going to depend on what the load is. So when you're looking here at 6 newtons, 6 newtons is, you know, about 12 times the typical load that would occur in the

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human body. If you look at a cough, for instance, that's about .5 newtons. So 6 newtons is a pretty heavy load.

When you look at the ideal designs of meshes, ordinarily, meshes are designed to withstand, you know, ideally 2 newtons. I think 6 newtons is not a physiologic load. So I'm not sure why they felt the need to apply that much force.

And in the second curve, they did as much as 14 newtons, which would be 28 times, you know, what you would see with normal everyday activity.

Q. (By Mr. Zonies) Do you see on -- just above the graphs you're looking at in Figure 5, the last sentence in the first column says, "The permanent elongation after C1, 10 cycles between .5 and 5 newtons, or roughly .1 and 1.1 pounds, of the Gynecare mesh was different from that of all the other samples tested. Gynecare samples permanently elongated by 17.5 plus or minus 4.2 percent indicating that although very little force applied, there is irreversible deformation of the TVT." Do you agree or disagree with that conclusion?

MS. SCHMID: Objection; foundation.

A. Gynecare provides samples, so these are the 8-centimeter samples, not 45 centimeters. So

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you got an 8-centimeter sample that's permanently elongated by 42 percent, which is basically the same as what the AMS mesh did, "and the tanged, nonheated portion of Boston Sci, 40 percent, Bard samples, again, displayed significantly less permanent elongation followed by Caldera and Mentor."

(Reviewing document.) So what the conclusion is is that the less-stiff meshes -- I'm sorry, the stiffer meshes are not going to elongate as much. I would agree with that conclusion. If the mesh is very stiff, you're not going to have as much elongation.

Q. And I'm particularly focused on the sentence, or the sentence that I read, which is concerning the very low load. So "The permanent elongation after C1, 10 cycles between .5 and 5 newtons, the Gynecare mesh was different from that of all the other samples tested. Gynecare samples permanently elongated by 17.5, plus or minus 4.2 percent, indicating that although very little force applied, there is irreversible deformation of the TVT." Do you agree or disagree with that statement?

MS. SCHMID: Objection; form, foundation.

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A. I thought I heard you say "very low loads." I'm not sure where it says that in that statement.

Q. (By Mr. Zonies) It says, "very little force applied"; do you see that?

A. I do see that, yes.

Q. So with very little force applied, there is irreversible deformation of the TVT. Do you agree or disagree with that statement?

MS. SCHMID: Objection; form, foundation.

A. I disagree with that statement.

Q. (By Mr. Zonies) Based upon what?

A. Based upon other papers that would not cite that this is a very low load. This is an everyday physiologic load, so I disagree that that's a very low load. There's a paper by Dr. Lynn, and there's other papers that -- the Dietz paper, for instance, that go over loads and the stress-strain curve. And I think the .5 newtons to 5 newtons is something that I see in the Dietz data and other papers, so I would disagree that .5 to 5 newtons is very little force. It might be in the grand scheme of things, but these are the forces that occur in the human body, so I think that they're not very low forces with respect

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to what the body's used to observing.

Q. So the .5 to 5 newtons are the forces that you would see in the human body?

A. That's correct.

Q. Those are the forces you would expect to see on a transvaginal mesh such as TVT-R, correct?

A. Well, it's a big range. I mean, you're talking about a tenfold range. So what I see typically is, you know, somewhere between .1 and .5 newtons. I would consider 5 newtons a huge amount of force. It says "very little force." 5 newtons is not very little force. 5 newtons is a very big force.

Q. You said, what you see. What do you mean when you say, from what you see, .1 and .5 newtons is what's typical?

A. That's based on my review of what's reported in other papers and in the medical literature. So I would disagree that 5 newtons is little force. 5 newtons is a big force.

Q. But you would agree that .5 to 5 newtons is what one would experience in the human body, correct?

A. .5, yes. 5, no. I'm not aware of what 5 -- what would constitute 5 newtons.

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Q. Okay. And but --
A. So what I mentioned earlier is .5 to maybe as much as 2 newtons, that's how the meshes are designed. Ideally, the meshes are designed -- if you look at the width of the urethra, it's 1 centimeter. And you can look at the width of the mesh being 1 centimeter, so you have to also account for the forces being distributed over that 1 centimeter. And when you take a mesh that can, say, withstand 8 newtons, and then you divide it by the 1-centimeter width, it's typically designed to withstand around 2 newtons. So I'm not surprised that they permanently elongated it when they stretched it to 5 newtons, which is much more than what the mesh is really designed to withstand.
So, you know, that's one of the limitations in dry-lab testing. But what I can say, if you go to the other figures, for instance, like Figure 3, you can see that the Gynecare mesh behaves very similar to the other meshes, especially the AMS mesh. And, you know, it's a mesh that has very little stiffness where when you compare it to some of the other products, like the Bard product, for instance, it's not nearly as stiff. The Caldera, the Mentor product, they had to put out a separate

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curve because they're so much stiffer than the other five products that are mentioned.
Q. And what does that mean to you clinically, that they're so much stiffer?
A. Well, there's a balance in surgery that you're going to look for when you're designing meshes. So you want something that's going to bend, but not break. So the fact that the Gynecare mesh can elongate underneath the urethra during physiologic loads, I feel that's a good thing. So as the woman is walking or jumping up and down or running, you want the urethra to descend, and you want the urethra to be mobile. If the mesh is too stiff, then that urethra is not going to move, and then you do worry about that causing complications. And so you want to have the optimal balance of stiffness.
And if you look at that physiologic range, you know, even going up as much as 10 newtons, there's a very linear response in terms of the elongation. It's not until you get to the nonlinear portions of the curve that the mesh starts to become stiff. So really up to 10 newtons, the mesh is not stiff at all. It's once it gets beyond 10 newtons that you'll start

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exhibiting some stiffness.
Q. So on the second page, the last -- on the first page of the Moalli study, the last two words are "for example"; do you see that?
A. Page 1?
Q. Yes.
A. Yes.
Q. "For example, one of the primary problems in using the TVT is that as a result of its low stiffness, the mesh easily deforms when tensioning under the urethra. Specifically pulling a sling gently results in thinning of the mesh, permanent deformation and fraying at the tanged edges"; did I read that correctly?
A. Yes, you did.
Q. And do you have any reason to disagree with that conclusion by Moalli, et al.?
MS. SCHMID: Objection; form, foundation.
A. Well, there's no reference to it, number one, so this is her thoughts on that. She says that it's a primary problem, but she doesn't cite what the problem is. I would say it's one of the primary advantages of the TVT, not that it's a problem, but that's an advantage. That's why it's, you know, the most commonly utilized product ever

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in the history of stress urinary incontinence surgery, more commonly used than any of the competitor meshes.
And I personally have pulled on these meshes, and you would have to pull quite hard to deform the mesh. So when she says "pulling on the sling gently results in thinning," that might occur if you take a 45-centimeter mesh and cut it into 8 centimeters and already start to mechanically alter it, but that's not my own personal experience when implanting the mesh.
Also, the mesh has a plastic sheath over it which protects it. But there's really no reason to pull on the mesh. When you place the mesh, your load from the bottom to top approach, it lies flat below the midurethra, you put your number -- Hegar dilator in there, you take the plastic sheath off, and you cut it at the skin. There's no reason to be pulling or deforming the mesh.
So I mean, what she's doing in this paper is interesting, and I think it helps sort of compare and contrast products, but meshes, in my practice, don't deform, so I don't know why we're intentionally trying to deform a mesh and then measure the biomechanical properties of a deformed

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mesh. Why not measure the biomechanical properties of a mesh that's not deformed.
Q. Doctor, do you know what DDSA stands for?
A. DDSA?
Q. Yes.
A. Is that in this paper?
Q. No.
A. I'm not immediately familiar with that DDSA.
Q. How about DFMEA?
A. I mean, I could -- it may be related to deformation, but I'm not familiar with the abbreviations. I'm probably familiar with the terminology, but not the abbreviation.
Q. Have you read any of the design files associated with the TVT-Retropubic?
A. Design files?
Q. Yes.
A. I read a number of Dr. Ulmsteen's original papers on TVT.
Q. Have you read any of Ethicon's design files on the TVT mesh?
A. I don't know if that is including Ulmsteen's data, but I've read Ulmsteen's original

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papers, the paper from '95, '98, the personal history he wrote about the tape and its developments. I'm familiar with the history of the mesh, but these design files, it sounds like you're referencing to a particular document that I'm not familiar with.
Q. Okay. What is a mesh fragment?
A. A mesh fragment I believe would be referring to a portion of the mesh that's not contiguous with the body of the mesh.
Q. And is it important to ensure that there are not mesh fragments in the vaginal space?
MS. SCHMID: Objection; form, vague.
A. I think whether the mesh is contiguous or not contiguous is -- it's still polypropylene, and it's going to perform similarly, whether it's in contact with the body or not in contact with the body, the mesh. So I don't have any concerns about fragments or fraying of the mesh.
Q. (By Mr. Zonies) So have you ever removed a mesh where -- a sling where there was encapsulation?
A. Certain slings, yes. If you looked at the ObTape product, which would be, really, a Type IV mesh similar to particle board, similar to

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Gor-Tex, a microporous mesh, and then certainly silicone products encapsulate, but I have not witnessed that with TVT mesh or Type I polypropylene mesh.
Q. What is a pseudocapsule?
MS. SCHMID: I'm sorry. Can you say that again?
MR. ZONIES: Pseudocapsule, p-s-e-u-d-o-c-a-p-s-u-l-e.
MS. SCHMID: Thank you.
A. So I think everyone's familiar with the term "capsule." When you put the word "pseudo" in front of it, it would mean that it kind of looks and behaves like a capsule, but anatomically it's not a true capsule. So people often use that term to describe the capsule around an implant, "pseudocapsule." Others would just use the word "capsule."
Q. (By Mr. Zonies) Would others use "encapsulated"?
A. Yeah, I think those words can be used interchangeably. So it's referring to some sort of capsule.
Q. In your article in 2013, you wrote that you encountered meshes that had pseudocapsule's,

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correct?
A. I have to look at the article.
(Exhibit 13 was marked for identification.)
Q. (By Mr. Zonies) I'll mark Exhibit 13, your article entitled "Surgical management of lower urine mesh perforation after midurethral polypropylene mesh sling." Do you have that in front of you, Doctor?
A. I do.
Q. This is an article you wrote discussing your treatment of a number of women who experienced severe complications associated with mesh slings, correct?
A. Correct.
Q. And you wrote in this article on page 2113, "In the past six years"; do you see that paragraph?
A. I do.
Q. You wrote, "In the past six years we have seen an increase in the overall number of transvaginal mesh complication cases referred to our center. This alarming increase prompted us to review our experience with transvaginal polypropylene mesh"; did I read that correctly?
A. Yes.

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Q. And you actually did have an alarming increase in the number of mesh complications during that period of time, correct?

A. Not me personally. I think what I stated was the cases that were referred to our center that I was asked to manage. So because of that, I wanted to go back and review my own experience. So I did that. If you read the next sentence, "Since 2006, midurethral sling placement by senior author BJF," which is me, University of Colorado Hospital, I have had three lower urinary tract perforations out of 600 cases. So that would be -- if it was 6 into 600, that would be 1 percent, so about 25 percent. So I was alarmed by what was being referred to me, but after I reviewed my own personal data, it was consistent with the medical literature and what other people were reporting.

Q. What was your loss to follow-up in those 603 cases?

A. I don't believe we lost any to follow-up. We reviewed all 600 cases. All these patients were, you know, followed for a year. We didn't call all 600 patients, but my practice, in general, patients will return to me.

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Q. What are your statistics on how many of your patients return to you? What are your actual statistics?

A. What I can state from other studies I've done on male urethral stricture disease, ureteral stricture disease, it's unusual that we would lose more than 5 percent of patients to follow-up.

Q. But do you know what your loss to follow-up was in these 600 patients that you're talking about in your paper?

A. So probably less than 5 percent.

Q. And you base that upon what statistics?

A. That's based on my review of other patient cohorts in my practice and patients behaving similarly, so, you know, we spent a lot of time in these depositions reviewing studies that I've published on various surgical procedures, whether that's male urethral stricture disease, ureteral stricture disease, mesh complications, pubovaginal sling, Prolift, artificial urinary sphincter. So that's been my experience in any of those studies. And I think that is consistent with this group of patients.

Q. How many of those 603 women did you call at one year?

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A. We saw them personally face-to-face, so we see them at two weeks, six weeks, three months and one year.

Q. How many of those 603 women did you see at two years?

A. The only patients that we were following after the one-year period would be patients that had other complaints and other reasons to be followed. The rest of them would be returned to follow-up with their local provider.

Q. How many of those 603 women did you see at two years?

A. I don't have that number.

Q. How many of those 603 women did you see at one year?

A. I would say close to probably 95 percent or maybe even greater.

Q. Where is that data?

A. Where is that data? That's my own personal review and my experience with other patients in my practices.

Q. Of those 603 women, it's your testimony here today that you saw 90-some percent of those women at one year?

A. That's an approximation, Mr. Zonies, but

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that's based on my experience with other cohorts.

Q. That's not based upon these 603 women, correct?

A. I'd have to go back and look at that, but I believe that number is representative.

Q. Why didn't you say that 5 percent of these women were lost to follow-up?

A. Again, those are estimations. You know, I'd have to go back and look at the review of those 600 patients.

Q. If it were 5 percent that were lost to follow-up, that'd be up to 30 women, and they all could have had an erosion, correct?

MS. SCHMID: Objection; form, calls for speculation.

A. No, that's not correct. I don't see any reason to believe why, you know, 30 out of 30 patients would have a .5 percent complication.

Q. (By Mr. Zonies) But you don't know?

MS. SCHMID: Same objection --

A. I'm confident --

MS. SCHMID: -- argumentative.

A. -- in saying that there's no possible way that all 30 of those patients had mesh perforation.

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Q. (By Mr. Zonies) You admit in this paper that "the original implanter may not have knowledge of the complex mesh complication that occurred in their patient."

And you agree with that, right? The original implanter may not know.

A. It depends on who the original implanter is. If the original implanter is not me, you know, I can't speak for how they follow their patients. I can just speak for how I follow my patients and what the FDA Public Health Notification recommended, that you do diligence in following your patients, and that's what I've done. I have all my cases recorded. I have my own registry. We don't go out and contact those patients, but if we needed to, we could.

Q. And in this paper, you say that there are complications that the meantime from initial placement of the mesh until removal was 15.5 months with a range from 1 month to 60 months, or five years, correct?

MS. SCHMID: I'm sorry. Where are you reading from, Counsel?

Q. (By Mr. Zonies) Next paragraph down, it says "The mean time." Do you have that, Doctor?

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A. Yeah, I do.

Q. So isn't it true, Doctor, that -- and you've testified before, I believe, that a mesh complication can occur at any time from the moment it's put in until the end of the woman's life, essentially, as long as the mesh is implanted, correct?

A. Yes, there's no finite range.

Q. And, in fact, you had at least one woman in this paper that had a complication after five years, correct?

A. Yeah. And if you look at statistics, some prefer to report the median rather than the mean. So when you look at the mean, we had someone at 60 months. That's going to drag that average up to 15 months. But what I've seen most consistently is patients presenting before one year. So the median may have been a better number to report. Median is the most common time where people report, so that's most common month, where mean just averages the entire range. So if you have one outlier, then that could really skew your data.

Q. But you agree that you've seen mesh complications in patients well beyond 15 and a half months, correct?

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A. Correct.

Q. And this alarming increase that you saw at your center of mesh complications, these were women where you actually treated them for a mesh complication. It was a real complication, correct?

MS. SCHMID: Object to form; compound.

A. However you want to describe it. There's 21 patients that we treated with lower urinary tract mesh perforation of which three of them were my patients, 18 were referred to me.

Q. (By Mr. Zonies) In other words, these are -- you wouldn't treat a woman who didn't have a true complication from her mesh. You wouldn't excise a mesh if a woman didn't actually have a complication, correct?

A. Are you asking me if I would excise an asymptomatic patient?

Q. Yes.

A. It would be very unlikely. There may be a scenario where someone doesn't have any symptoms, but if the mesh is in the lower urinary tract, and when you look at the table, you know, in the study, all of these patients that we excised were, in fact, having symptoms. That's reflected in Table 1 with the common symptoms that patient's presented

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with.

Q. And the most common being pain and dyspareunia, correct?

A. I don't believe we separated the -- so pain was the most common, and then, this is in Table 1, pain was most common followed by urinary incontinence, number 2. Urethral obstruction was number 3. Dyspareunia was probably 4 or 5, but pain was number one.

Q. And you write in your paper on the last page -- or, I'm sorry, on page 2116 that "A review of the contemporary literature on the surgical management of LUT mesh perforation did not reveal any consensus on how to effectively manage mesh complications." That's what you wrote, correct?

A. And it's in Table 4. And what that is reflective of is that there's quite a bit of heterogeneity in how these complications were being managed across various centers.

Q. And that's as of 2013 that there was no real consensus on how to manage them. In fact, that's, in part, why you wrote this paper, correct?

A. I agree with the first part of the statement, that there's no consensus. The reason I wrote the paper is just to tell people what we did,

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how we managed it.
Q. And as you sit here today, there still is no real consensus on how to manage mesh complications, correct?
MS. SCHMID: Objection; form, vague.
Go ahead.
A. I've been involved in two recent panels, one at SUFU and one at the AUA with other experts, and I believe that what we're doing now does have some consensus. That would consist of removing the mesh from the urethra, repairing the defect in the urethra. Those two procedures are consistent across a number of practices. Most experts on the panel do not recommend removing the entire mesh. Where the variability and technique would be is whether or not you need to place a flap or a new biological sling at the same time of the mesh removal. That's where there's variation in the procedures, so under the column "Additional Procedures" versus primary procedure.
Q. Have you personally ever reported a mesh complication into the FDA's database?
A. I don't believe so.
Q. And how many mesh complications have you handled?

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MS. SCHMID: Objection; form, vague.
A. Over 200.
Q. (By Mr. Zonies) So that database is short 200?
MS. SCHMID: Objection; form, argumentative.
Q. (By Mr. Zonies) Just from your practice?
MS. SCHMID: Sorry about that.
MR. ZONIES: That's okay.
MS. SCHMID: Objection; form, argumentative, assumes facts not in evidence.
A. Not necessarily. Since you could see in that paper the overwhelming majority of the patients are referred to me. The original implanter may have reported the complication to the databank. So that's making an assumption that I didn't report it and the original implanter didn't report it or anybody else who maybe have been involved in the care.
Q. (By Mr. Zonies) One of your opinions is that the IFU adequately warned physicians of the relevant adverse effects, correct?
A. Correct.
Q. Which IFU did you look at for that? Did you know?

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A. I believe I looked at both of them. I think there's one from 2005 and then 2008. I'd have to get them in front of me, but I feel both IFUs were adequate.
Q. And your reliance list actually identifies those IFUs that you just discussed.
Are you aware, Doctor, that in 2015, Ethicon came out with a new IFU for the TVT-Retropubic?
MS. SCHMID: Objection; form.
Go ahead.
A. I'm unsure.
Q. (By Mr. Zonies) Nobody ever gave you the 2015 IFU to review?
A. Well, they don't have to give it to me. It's included in the package.
Q. But you haven't used the TVT-R in six years, right?
A. I use the TVT-Exact. That's what I mentioned earlier. So when you say the IFUs changed, are you referring to TVT-Exact or TVT classic?
Q. Yes, the one we're talking about today, the TVT-Retropubic device.
A. Then no, I haven't seen it.
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(Exhibit 14 was marked for identification.)
Q. (By Mr. Zonies) I'm going to hand you Exhibit 14. And you'll see on that first page on the left-hand side at the bottom, it says the date is 01/2015. Do you see that date?
A. Yes.
Q. And this is the TVT-Retropubic instructions for use that if you go on the Web you can actually pull these down.
A. Okay.
Q. And Doctor, you're now reviewing Exhibit 14, the 2015 IFU. Can you confirm that you've never seen that IFU before?
A. I can't confirm either way. I've looked at a number of IFUs. I've included them on the USB and on my reliance list.
Q. And if it's not on the USB or your reliance list, you haven't reviewed it, correct?
A. I'm unsure, is what I mentioned.
Q. Doctor, do you know if you ever used the TVT-Retropubic laser-cut device?
A. Yes, I have.
Q. How do you know that?
A. Because when you look at the history of mechanical cut versus later cut, the mesh was

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mechanical cut up until around 2006. And as I mentioned earlier in the deposition, I didn't start using the TVT-Exact until around '11, so probably from around 2006 to '11 I was using the laser-cut mesh.

Also, as I mentioned earlier in other depositions, they would mark the box with an L, and they did that for TVT-O as well as retropubic TVT. And I believe that's what was offered to my hospital. But I'm confident that when the laser cut came out, that's when the hospital switched over from mechanical to laser.

Q. So do you believe that if I find the hospital's records for its purchasing of TVT-Retropubic devices, that in or around 2006, all of the TVT-Retropubic devices that the hospital purchased will have been laser cut?

MS. SCHMID: Objection; misstates prior testimony.

Go ahead.

A. Working at a number of different hospitals, so it would probably be particular to that hospital, but I believe that's in and around the time when we switched to laser cut.

And also, with the Gynecare TVT-Secur and

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TVT-Abbrevo, TVT-Exact, they're all laser-cut products, so certainly I've used laser cut.

Q. (By Mr. Zonies) Was there a problem with the mechanically cut mesh that made you want to switch to the laser-cut mesh?

A. I wouldn't use the word that there was a problem. I think that there were some distinct advantages offered with laser cut that were attractive and seemed intuitive to offer an advantage. And if you looked at what some of the competitors were doing with their products, they were using the laser cut or what's also known as the nontanged edges, and so they were looking to heat-seal the edges. Boston Scientific did that, and some of the other companies did that. And what that led to was easier deployment of the mesh, so when you placed the mesh, it was less likely -- I mean, I should just say it was easier to deploy the mesh to get it to lie flat. And it just seemed to be easier to handle.

Q. Were you aware, Doctor, that as late as 2008, 90 percent of TVT sales were actually mechanically cut mesh, not laser cut?

MS. SCHMID: Objection; form, assuming facts not in evidence.

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A. I never really kept track of what the sales data was. I paid attention to what I used in my practice. Again, around 2008 or '9, I went to TVT-Secur, and that was accounting for, like, 80, 90 percent of the midurethral slings that I implanted, so overwhelmingly, the majority of meshes that I was implanting after 2008 were laser-cut meshes.

Q. (By Mr. Zonies) But I'm talking specifically about the TVT-Retropubic.

Is it your testimony that you actually have a recollection of using a TVT-Retropubic that had an L on the end of the number?

A. I know certainly for TVT-O that we saw that. I mentioned I did 75 of the TVT classic, so it was never my most common procedure.

Q. Okay. So you're not sure if you ever used a laser cut for the TVT-Retropubic?

A. I can't say for a hundred percent certainty.

Q. And you likewise can't say for certain what other doctors used, whether it was laser cut or mechanically cut, correct?

MS. SCHMID: Objection; form, vague.

A. Conversations I had with colleagues,

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both at prof ed events and at meetings, it seemed to me that most of the midurethral sling surgeons, people were transitioning to laser cut, especially friends that I had that were using the Boston Scientific product.

Q. (By Mr. Zonies) You've never seen a clinical study assessing TVT-Retropubic mechanically cut mesh as compared to TVT-Retropubic laser-cut mesh, correct?

A. A head-to-head?

Q. Yes.

A. Not a head-to-head. But what I have seen is systematic reviews that include patients from the earlier years versus reviews that have been compiled from patients that have been implanted more recently. When you look at the Cochrane review, the Schmipff review, those studies, you know, you have a mix of laser cut and mechanical cut. When you look at Tommaselli, you have TVT-O versus TVT-Secur, a mechanical cut versus a laser cut. They're not true head-to-head, you know, TVT-R mechanical cut to TVT-R laser cut, but I think you can infer from the literature and the systematic reviews, you can look at the complication rates and the efficacies of the

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products.
Q. Well, and even Tommaselli, using TVT-S laser cut, has much lower efficacy than does the TVT-Retropubic, correct?
MS. SCHMID: Objection; form, foundation.
A. I would disagree with that. Again, it comes back to what the outcome measures are, if they're looking at just subjective outcome measures versus objective outcome measures versus you got to be two for two to be considered cured. So if the objective measures are more rigorous, you're going to have a lower efficacy rate reported.
Q. (By Mr. Zonies) You have no idea in any of the studies in the Cochrane review which of the TVT-Retropubics in those studies was laser cut and which of the TVT-Retropubics was mechanically cut; isn't that true?
A. What my testimony was that you can look at the years that the patients were implanted, and you could understand what products were used based on the years. Studies that were before 2006, then all of those patients were mechanical cut. Then there's a transition period. And then in more recent studies, then laser cut.
Q. How do you know that?

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A. Based on what was available to surgeons and based on conversation with colleagues and people in prof ed. And it really seemed to me that when laser cut came out, that was because there was interest in that, and there was a need, and that's what implanters desired. So, you know, that's what Ethicon TVT users desired. So I got to believe that they went ahead and used the laser-cut mesh.
Q. Okay. But you have no actual support for that other than you got to believe, correct?
MS. SCHMID: Objection; form, misstates prior testimony.
A. Again, what I stated earlier was conversation with colleagues at meetings, at prof ed events, within my hospital. If I talked to my partners, I asked them what they're using. And it seemed overwhelmingly that people were switching to laser cut.
(Exhibit 15 was marked for identification.)
Q. (By Mr. Zonies) I'm going to hand you Exhibit 15, Dr. Flynn. This is an internal Ethicon document. Have you ever seen this document before?
A. It looks familiar to me. I believe I probably have seen some of this. Some of the comments in here look familiar, but I don't see a

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title on this document, really, unless the title's "Things to Consider." Who wrote this document? Dan Smith?
Q. You know Dan Smith, right?
A. I know the name. I don't know him personally.
Q. So as of the end of 2008, if you look at the tenth bullet point down in Ethicon's internal document, what does that say?
MS. SCHMID: What? I'm sorry. What page are we on, Counsel?
Q. (By Mr. Zonies) First page, tenth bullet down, it starts with "Most surgeons who use TVT"; do you see that?
A. "Most surgeons who use TVT products do not know if what they use contains mechanical-cut or laser-cut mesh. Additionally, they don't know we have laser-cut TVT and TVT-O products on the market. 90/10 versus MC versus LC sales," so this is an article, or this is data from 2008. So this would be, I guess, one to two years after laser cut became available.
Q. (By Mr. Zonies) Right. So two years after laser cut becomes available, Ethicon's own internal document says that most doctors don't know

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which one they're using, and, in fact, 90 percent of them are using mechanically cut. Isn't that what it says?
MS. SCHMID: Objection; foundation.
A. That's what it says, and that may be true, because most doctors don't care, because mechanical cut and laser cut are essentially the same. So doctors are very comfortable either way, whether it was mechanical cut or laser cut.
Q. (By Mr. Zonies) So we do know, then, that of the studies that were done up and through patients in 2008, 90 percent of those were mechanically cut, right?
MS. SCHMID: Objection.
A. It looks like --
MS. SCHMID: Objection; form, misstates prior testimony.
A. So this is Dan Smith's approximation. Dan Smith's an engineer. I don't believe Dan Smith works in sales and marketing, so this is an engineer's approximation of what the market is.
Q. (By Mr. Zonies) Based on sales.
A. I'd be interested to see where he got the data.
Q. Have you ever asked Ethicon for that, or

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have they ever shared it with you?
A. What was shared with me at the prof ed events and courses were that most surgeons were interested in laser cut. That's what was shared.
Q. Will you ask Ethicon for that sales data, Doctor, so you can take a look at it? And that might impact your opinion, right?
MS. SCHMID: Objection; form, argumentative.
A. I think what my opinion is in the report, and what's been consistent, is that mechanical cut and laser cut behave similarly. And so I don't feel a need to spend a lot of time teasing out what the sales data was in 2008, because what the literature shows is that the products have behaved similarly based on efficacy and safety.
Q. (By Mr. Zonies) But you don't have a single piece of literature that you can cite to, Doctor, where the only difference between the two devices being compared is whether it's mechanically cut or laser cut, right? There's not one study that does that, is there?
A. I think if you look at the literature based on products that came only as laser cut, for instance, TVT-Secur, TVT-Abbrevo, TVT-Exact, and

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you compare those to the TVT studies that were published before 2006, you've just created a comparison. And at least with respect to safety, meaning vaginal exposures, lower urinary tract perforations, dyspareunia and pain, they performed very similarly. If you look at dyspareunia, for instance, the incidence of dyspareunia after midurethral sling is .5 percent, and that number resonates whether that is a laser-cut mesh or a mechanical-cut mesh.
MR. ZONIES: Move to strike as nonresponsive.
Q. (By Mr. Zonies) Doctor, can you identify a single study where the only difference between the two devices being compared is whether it's laser cut or mechanically cut? One study.
A. One study that has both cohorts head to head in the same paper? I'm not aware of that study.
MR. ZONIES: I'll reserve the remaining time for recross.
MS. SCHMID: What time is left?
MS. COVINGTON: I have 17 minutes.
MS. SCHMID: Let's go ahead and take a break.

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(Recess taken from 4:31 p.m. until 4:50 p.m.)
EXAMINATION
BY MS. SCHMID:
Q. All right. Good afternoon, Dr. Flynn.
A. Good afternoon.
Q. You'll recall you were asked a couple of questions about an abstract that you had prepared which was marked as Exhibit Number 10. And was this abstract ever then published in a peer-reviewed journal, Dr. Flynn?
A. The abstract was published in the journal Urology, but there was no manuscript that was later published that accompanied this abstract. So what the AUA does is all of their abstracts that are accepted to their meeting are published in their journal, which is a supplement, so you can see on the top of this exhibit, it says "Volume 189, Supplement." So they have a supplement to their journal where all these abstracts exist.
Q. And did this abstract -- and I apologize, my question was not clear, so let me start again.
Did this abstract, which was marked as Exhibit Number 10, ever then become published?

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A. No, it did not.
Q. And why not?
A. Well, because there was no statistical significance with these conclusions. So when we prepare a paper in an abstract, sometimes we'll publish something just to report some results, and other times, like you can see, you know, in an abstract right next to it on the same page where there's P values and standard deviations and more rigorous statistical analysis, and we didn't have that in our paper. Our paper wasn't properly powered. It was only 50 mesh revision surgery cases, and so because of that, it wouldn't have met the standards of a peer-reviewed journal. So it wouldn't have been publishable. So generally, we don't attempt to publish things that we don't think are going to get published.
Q. Can you, Dr. Flynn, pull up in front of you Exhibit Number 12, please? And that was the Pam Moalli article.
A. Yes. So this is Exhibit 13, and here's Exhibit 12.
Q. Okay. So just on Exhibit Number 12, my next questions.
A. Yes.

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Q. Okay. You recall you were asked a series of questions about the Moalli paper, correct?
A. Correct.
Q. And did the authors identify what they considered in this paper to be the gold standard for midurethral slings?
MR. ZONIES: Object to the form.
A. They did.
Q. (By Ms. Schmid) And what product did they identify as the gold standard for midurethral slings?
MR. ZONIES: Same objection.
A. Well, if you go to page 656, the second paragraph in the right column, it says, "For simplicity of data presentation, we used the Gynecare TVT as the gold standard and defined the behavior of 5 newer versions of the midurethral sling relative to it."
Q. (By Ms. Schmid) Okay. So in the Moalli paper, they refer to the Gynecare TVT midurethral sling as the gold standard, correct?
MR. ZONIES: Object to the form.
A. They did. And then if you look at the tables and figures throughout the paper and all of

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the P values and comparisons they make, everything's compared to the Gynecare TVT device.
Q. (By Ms. Schmid) All right. And Dr. Flynn, you were asked a series of questions this afternoon about the differences between mechanically cut mesh and laser-cut mesh; do you recall those questions?
A. I do.
Q. And specifically you were asked whether there was ever a head-to-head comparison in a single paper of the performance from a safety and efficacy standpoint of mechanically cut mesh versus laser-cut mesh. Do you recall those questions?
A. I do.
Q. Okay. And there is no such paper that makes that head-to-head comparison; is that correct?
A. That's correct.
Q. So how do you, then, Dr. Flynn, have confidence in your opinion that the laser-cut and mechanical-cut mesh are both safe and effective meshes?
MR. ZONIES: Object to the form.
A. Well, I've implanted over 800 midurethral slings. And I've been using

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midurethral slings since 2004. So I've used both mechanical-cut and laser-cut mesh. That's what was taught to me as a resident and fellow and what I incorporated in my practice. So from my own clinical experience from 2004 to 2006, maybe even later, 2008, when using mechanical-cut mesh, I got excellent results. I had over 90 percent success with a complication rate of somewhere around 2 to 2 and a half percent.
Later in my practice I switched over to laser-cut mesh both in the TVT-Obturator form and TVT-Exact, TVT-Abbrevo, TVT-Secur. I mentioned I used the Boston Scientific Advantage Fit, and all of these products performed quite similarly in terms of having efficacy and safety that was very similar to the mechanical-cut.
So after doing 800 cases, I'm very comfortable commenting on both of the meshes. I found the way they resulted in my patients and the outcomes I got were quite similar.
My review of the medical literature, including systematic reviews, meta-analyses, more recent publications, for instance, like the Tommaselli paper or papers that are more specific reflecting later products on the results again, are

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similar to what was reported in some of Ulmsteen's original papers. Conversations with colleagues at my hospital, in my group, going to meetings, prof ed events, those are the similar responses and feedbacks that I've received.
So there's been over three million TVT products implanted in patients over a 20-year period, and many of those were mechanical cut, many of them were laser cut. But, you know, there's no data to support one product works better than the other, or one product is inferior than the other. So I got to believe there would be a paper somewhere that would show some really unusual results with laser cut or with mechanical cut if there was some outlier. And I'm not aware of such a paper.
Q. (By Ms. Schmid) You have been asked today in your deposition to provide your expert opinions on the TVT classic, correct?
A. Correct.
Q. And your opinions are all set forth in your expert report which was marked earlier today as Exhibit Number 4, correct?
A. Correct.
Q. And can you tell the jury what you have

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relied upon as the bases for your expert opinions regarding the TVT classic or the TVT-Retropubic mesh?

MR. ZONIES: Object to the form.

A. So what I outlined in my report and on my reliance list is over 100 different publications that pertain to mesh and stress urinary incontinence. My report starts out with my background and qualifications. It mentions, you know, my titles as an expert in female pelvic medicine and reconstructive surgery. I'm Board certified in that area. And I'm an associate professor at University of Colorado.

As the report goes through, I overview the beginnings of the TVT product as developed by Dr. Ulmsteen. I think those are the important papers that help you understand the development of the product.

If you look at TVT, it was really a product that was first done by a very esteemed, skilled professor that then brought the product to six ordinary Scandinavian units, and they essentially got the same results in terms of efficacy and safety. So those earlier papers I think were very supportive of the device. The product then came to

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the United States and performed equally well.

Later, you know, five, ten, fifteen years later, we now have over 100 RCTs. We have over 1,000 publications. We have systematic reviews. We have meta-analyses. So we have Level I evidence supporting the use of the TVT product. So those are the studies that I relied on in preparing my report.

Q. Is there anything else that you have relied on as a basis for your opinions other than what you just described?

MR. ZONIES: Object to the form.

A. Well, certainly I rely on my own clinical experience. I'm a high-volume surgeon. I do four to five hundred operation as year. I've been doing that for the last 15 years. 85 percent of my job is clinical, meaning taking care of patients, talking to women with incontinence and prolapse, and performing surgery. So I feel that I'm, you know, well-positioned to make statements in regards to these products because I've been using midurethral slings for almost 15 years now in my practice.

I've been teaching residents and fellows and medical students about the value of the midurethral

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sling. I participate in scientific meetings. I go to more than five or six meetings a year where I commonly hear about incontinence procedures. I listen to experts. I participate in panel discussions. You can see that on my CV. My CV is more than 50 pages long, and that itemizes all the abstracts, all the publications, all the presentations, textbook chapters I've written, videos and other forms of multimedia.

So it really comes down to my review of the literature, my personal experience with the device, and just feeling very well-connected with colleagues and experts, both at the AUA and at SUFU, at the AUGS. Reviewing those professional statements are very powerful. We review those commonly in our journal clubs, and those statements are ones that I use in my practice when talking about these products with patients.

And, you know, just to quote the American Urologic Association the full-length retropubic or transobturator midurethral sling Type I polypropylene mesh is the gold standard. And the TVT classic meets all those criteria. It's a Type I mesh. It has large pores. It has the optimal amount of elasticity. It's the right

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width. It's a full-length sling. So it has all those characteristics that I look for and that others have reported on when reporting on midurethral slings. It meets the criteria that the professional societies mention in terms of, you know, products that we -- that they endorse and that they support.

Q. (By Ms. Schmid) Did you bring with you your resume to today's deposition?

A. I did.

Q. And did you bring with you your reliance list to today's deposition?

A. I did. And the resume or CV has been marked as an exhibit. And I believe that was Exhibit 1 or 2.

Q. All right.

A. And then my reliance list is just after my report in this first binder. And that was printed on March 2nd. And I don't have the exact number of pages, but it's probably at least 30 to 40 pages of the reliance list.

MS. SCHMID: I have no further questions for you. Thank you, Dr. Flynn.

THE WITNESS: Thank you.

MR. ZONIES: Just a few follow-ups,

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Dr. Flynn.

EXAMINATION

BY MR. ZONIES:

Q. The abstract that you were discussing, your abstract, was it -- did you ever submit it to any journals for publication?

A. Well, just to be clear, again, the abstract was submitted to the American Urologic Association. It was accepted at that meeting, and they published those abstracts, so however you'd want to characterize that. Did I ever submit a full manuscript to any journal that accompanied that abstract? The answer would be no.

Q. That paper was never rejected for publication, or --

A. The paper was never written.

Q. You said that that paper was criticized by some. Who criticized the paper, the abstract?

A. Anthony Schaeffer, who is a urologist at Northwestern University. He was probably the most critical of the scientific method. Dr. Schaeffer has expertise in infectious-disease issues in urology. There was two moderators, I can't remember who the moderators were that day, but they

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both had some concerns about the methods, but I would have to go back and look at who moderated that session. I don't remember the names, but usually there's only opportunity for a few people to make comments, and if one person makes a lot of comments, then that prevents other people from having the time to make comments, so Dr. Schaeffer made the majority of the comments.

Q. And, in particular, the criticisms were that the methods were not reliable methods, correct?

A. He was concerned that we didn't do vaginal swabs at the same time to try to correlate what the vaginal swabs showed in relation to what the mesh culture showed. And Patrick Culligan and others have done similar papers, so he asked me to consider the shortcomings of those papers if we were going to pursue this paper further. So he had proposed a number of ideas to me that would have allowed me to maybe answer some of the questions that he felt were not answered by the abstract.

Q. And are you doing vaginal swabs now as you're testing explants?

A. No, that was just a recommendation specific to this paper.

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Q. You were asked questions about mechanically cut versus laser cut. Do you recall those questions?

A. I do.

Q. Of the 75 TVT-Retropubic devices that you've implanted, how many were laser cut?

A. Doing a calculation, rough calculation in my mind, probably close to half and half. I used the mechanical-cut product -- I used the retropubic product from 2004 to '11, so that's a seven-year period, so let's say there's ten a year. And then in 2006, when laser cut, we switched over maybe 2007, so that was probably 20 to 30 mechanical cut and that many laser cut with respect to the retropubic product.

Q. But that's just based upon which years you used the devices, correct?

A. Yeah, and similar with TVT-O, that was the product I was using more commonly earlier in my practice from 2004 to 2008 or '9, so I had used quite a bit of mechanical-cut mesh, but it was mostly in the TVT-O product.

Q. And do you have a case -- does your case log identify whether or not it was laser cut or mechanically cut mesh that you implanted?

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A. It does not.

Q. So you have no way to know for certain -- isn't it true, Doctor, that all of those TVT-Retropubics could have been mechanically cut?

MS. SCHMID: Objection; form.

Q. (By Mr. Zonies) Isn't that possible?

MS. SCHMID: Misstates prior testimony.

A. I don't think it's possible, because from what I recall, and my conversations with Ethicon and the local rep, I believe they had switched over the stock at the hospitals I operated at to laser cut.

MR. ZONIES: Thank you, Doctor. I have nothing further. I appreciate your time.

THE WITNESS: Thank you.

MS. SCHMID: We'll read and sign. Thank you.

MR. ZONIES: We'll take a rough.

(Whereupon, the deposition was concluded at 5:08 p.m. on April 19, 2016.)

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ERRATA

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ACKNOWLEDGMENT OF DEPONENT

I,_____, do hereby certify that I have read the foregoing pages, and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

_____

BRIAN J. FLYNN, M.D. DATE

Subscribed and sworn to before me this _____ day of _____, 20____.

My commission expires:_____

_____

Notary Public

REPORTER'S CERTIFICATE

STATE OF COLORADO)

) ss.

COUNTY OF DENVER)

I, MELANIE L. GIAMARCO, do hereby certify that I am a Registered Professional Reporter and Notary Public within the State of Colorado; that previous to the commencement of the examination, the deponent was duly sworn by me.

I further certify that this deposition was taken in machine shorthand by me at the time and place herein set forth, that it was thereafter reduced to typewritten form, and that the foregoing constitutes a true and correct transcript of the proceedings had.

I further certify that I am not employed by, related to, nor of counsel for any of the parties herein, nor otherwise interested in the result of the within litigation.

In witness whereof, I have affixed my signature and seal this 22nd day of April, 2016.

Melanie L. Giamarco
Registered Professional Reporter
Registered Merit Reporter
Certified Realtime Reporter

My commission expires: August 25, 2017.